US3112192 (Prod: Medical Center For Clinical Research - M3 Wake Research)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:08:42

All time stamps listed in this document are displayed in GMT

US3112192
Form: Participant Creation
Data signed: (b) (4) **02 Apr 2021 21:12:52**
Generated On: 09 Jun 2021 15:08:42

Participant ID	US3112192

mRNA-1273-P301 Completion Guidelines

FDA-CBER-2022-1614-0507548

US3112192
Folder: Screening
Form: Visit Date
Data signed: (b) (4) **19 Feb 2021 16:58:53**
Generated On: 09 Jun 2021 15:08:42

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	11 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	SCRN

FDA-CBER-2022-1614-0507549

US3112192
Folder: Screening
Form: Demographics
Data signed: (b) (4) **19 Feb 2021 16:58:53**
Generated On: 09 Jun 2021 15:08:42

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

FDA-CBER-2022-1614-0507550

US3112192
Folder: Screening
Form: Enrollment
Data signed: (b) (4) **19 Feb 2021 16:58:53**
Generated On: 09 Jun 2021 15:08:42

Date of Informed Consent *(dd MMM yyyy)*	11 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-2022-1614-0507551

US3112192
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Data signed: (b) (4) **19 Feb 2021 16:58:53**
Generated On: 09 Jun 2021 15:08:42

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

US3112192
Folder: Screening
Form: Medical History Summary
Data signed: (b) (4) **19 Feb 2021 16:58:53**
Generated On: 09 Jun 2021 15:08:42

Were any significant conditions reported?	Yes ■ No ☐

FDA-CBER-2022-1614-0507553

US3112192
Folder: Screening
Form: Medical History (1)
Data signed: (b) (4) **19 Feb 2021 16:58:53**
Generated On: 09 Jun 2021 15:08:42

Condition	BOWEL BLOCKAGE
Start date (dd MMM yyyy)	UN APR 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ■ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	APR 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-0507554

US3112192
Folder: Screening
Form: Medical History (2)
Data signed: (b) (4) **19 Feb 2021 16:58:53**
Generated On: 09 Jun 2021 15:08:42

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN APR 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	APR 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-0507555

US3112192
Folder: Screening
Form: Medical History (3)
Data signed: (b) (4) **19 Feb 2021 16:58:53**
Generated On: 09 Jun 2021 15:08:42

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

FDA-CBER-2022-1614-0507556

US3112192
Folder: Screening
Form: Medical History (4)
Data signed: (b) (4) **19 Feb 2021 16:58:53**
Generated On: 09 Jun 2021 15:08:42

Condition	ATRIAL FIBRILLATION
Start date (dd MMM yyyy)	UN APR 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes ■ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	APR 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-0507557

US3112192
Folder: Screening
Form: Medical History (5)
Data signed: (b) (4) **19 Feb 2021 16:58:53**
Generated On: 09 Jun 2021 15:08:42

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ■ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-0507558

US3112192
Folder: Screening
Form: Medical History (6)
Data signed: (b) (4) **19 Feb 2021 16:58:53**
Generated On: 09 Jun 2021 15:08:42

Condition	GALL STONES
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

FDA-CBER-2022-1614-0507559

US3112192
Folder: Screening
Form: Medical History (7)
Data signed: (b) (4) **19 Feb 2021 16:58:53**
Generated On: 09 Jun 2021 15:08:42

Condition	CHRONIC NECK PAIN
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Start Year (derived)	2012
Stop Month and Year (derived)	
Stop Year (derived)	

US3112192
Folder: Screening
Form: Medical History (8)
Data signed: (b) (4) **19 Feb 2021 16:58:53**
Generated On: 09 Jun 2021 15:08:42

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-0507561

US3112192
Folder: Screening
Form: Medical History (9)
Data signed: (b) (4) **19 Feb 2021 16:58:53**
Generated On: 09 Jun 2021 15:08:42

Condition	ASTHMA
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-0507562

US3112192
Folder: Screening
Form: Medical History (10)
Data signed: (b) (4) **19 Feb 2021 16:58:53**
Generated On: 09 Jun 2021 15:08:42

Condition	COLON POLYPS
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-0507563

US3112192
Folder: Screening
Form: Medical History (11)
Data signed: (b) (4) **19 Feb 2021 16:58:53**
Generated On: 09 Jun 2021 15:08:42

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-2022-1614-0507564

US3112192
Folder: Screening
Form: Vital Signs
Data signed: (b) (4) **19 Feb 2021 16:58:53**
Generated On: 09 Jun 2021 15:08:42

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	11 AUG 2020
Time of assessment *(00:00-23:59)*	12:07 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 12:07
Height *(xxx.x)*	63 in
Weight *(xxx.x)*	171.8 lb
BMI *(xxx.x)*	30.49664 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-2022-1614-0507565

US3112192
Folder: Screening
Form: Physical Examination
Data signed: (b) (4) **19 Feb 2021 16:58:53**
Generated On: 09 Jun 2021 15:08:42

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	11 AUG 2020

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

FDA-CBER-2022-1614-0507566

US3112192
Folder: Screening
Form: Childbearing Potential
Data signed: (b) (4) **19 Feb 2021 16:58:53**
Generated On: 09 Jun 2021 15:08:42

Date of assessment *(dd MMM yyyy)*	11 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)*	UN UNK 1978
Date of surgery unknown	False
If Post-menopausal, date of last menstruation *(dd MMM yyyy)*	
Date of last menstruation unknown	False

FDA-CBER-2022-1614-0507567

US3112192
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **19 Feb 2021 16:58:53**
Generated On: 09 Jun 2021 15:08:42

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

FDA-CBER-2022-1614-0507568

US3112192
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **19 Feb 2021 16:58:53**
Generated On: 09 Jun 2021 15:08:42

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	

US3112192
Folder: Visit 1 Day 1
Form: Visit Date
Data signed: (b) (4) **12 Feb 2021 21:01:30**
Generated On: 09 Jun 2021 15:08:42

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	11 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT1

FDA-CBER-2022-1614-0507570

US3112192
Folder: Visit 1 Day 1
Form: Randomization
Data signed: (b) (4) **12 Feb 2021 21:01:30**
Generated On: 09 Jun 2021 15:08:42

What was the date of randomization? *(dd MMM yyyy)*	11 AUG 2020
What was the participant's randomization number?	185678
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-2022-1614-0507571

US3112192
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Data signed: (b) (4) **12 Feb 2021 21:01:30**
Generated On: 09 Jun 2021 15:08:42

Height	ND - Not Done
Weight	ND - Not Done

FDA-CBER-2022-1614-0507572

US3112192
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **12 Feb 2021 21:01:30**
Generated On: 09 Jun 2021 15:08:42

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)*	11 AUG 2020
Time of assessment *(00:00-23:59)*	12:07 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 12:07
Temperature *(xxx.x)*	98.9 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	62 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	76 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-0507573

US3112192
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **12 Feb 2021 21:01:30**
Generated On: 09 Jun 2021 15:08:42

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)*	11 AUG 2020
Time of assessment *(00:00-23:59)*	13:20 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 13:20
Temperature *(xxx.x)*	99.1 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	66 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	74 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-0507574

US3112192
Folder: Visit 1 Day 1
Form: Physical Examination
Data signed: (b) (4) **12 Feb 2021 21:01:30**
Generated On: 09 Jun 2021 15:08:42

Was the physical examination performed?	Yes ☑ No ☐
Date of examination *(dd MMM yyyy)*	11 AUG 2020

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

FDA-CBER-2022-1614-0507575

US3112192
Folder: Visit 1 Day 1
Form: Exposure
Data signed: (b) (4) **12 Feb 2021 21:01:30**
Generated On: 09 Jun 2021 15:08:42

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)*	11 AUG 2020
What was the treatment time? *(00:00-23:59)*	12:48 (24 HR)
Treatment Date and Time (derived)	11 AUG 2020 12:48
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-2022-1614-0507576

US3112192
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Data signed: (b) (4) **12 Feb 2021 21:01:30**
Generated On: 09 Jun 2021 15:08:42

Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	11 AUG 2020
Collection time *(00:00-23:59)*	12:28 (24 HR)
Collection date and time (derived)	11 AUG 2020 12:28

FDA-CBER-2022-1614-0507577

US3112192
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **12 Feb 2021 21:01:30**
Generated On: 09 Jun 2021 15:08:42

Collection date *(dd MMM yyyy)*			11 AUG 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:22	11 AUG 2020 12:22
Nasopharyngeal Swab 2	No		

FDA-CBER-2022-1614-0507578

US3112192
Folder: Visit 1 Day 1
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 21:01:30**
Generated On: 09 Jun 2021 15:08:42

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

FDA-CBER-2022-1614-0507579

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:08:42

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**	99.1 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	11 AUG 2020 13:22
PC Open Date & Time	11 AUG 2020 13:08
PC Close Date & Time	11 AUG 2020 15:38

FDA-CBER-2022-1614-0507580

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.5 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ■ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	11 AUG 2020 20:00
PC Open Date & Time	11 AUG 2020 16:33
PC Close Date & Time	12 AUG 2020 11:59

FDA-CBER-2022-1614-0507581

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:08:42

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**	98.6 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ■ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	12 AUG 2020 14:39
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

FDA-CBER-2022-1614-0507582

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 3

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ■ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	13 AUG 2020 22:27
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

FDA-CBER-2022-1614-0507583

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 4

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ☐ No ☐
Please record your **TEMPERATURE in °F**	
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	
To **PREVENT** pain or fever from occurring	
PC Time Stamp	
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

FDA-CBER-2022-1614-0507584

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 5

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.5 °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	15 AUG 2020 16:27
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

FDA-CBER-2022-1614-0507585

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 6

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.9 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	17 AUG 2020 09:24
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

FDA-CBER-2022-1614-0507586

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 7

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.6 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	18 AUG 2020 11:07
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

FDA-CBER-2022-1614-0507587

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 1, 30 MINUTES AFTER VACCINATION (AT STUDY CLINIC)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	11 AUG 2020 13:24
PC Open Date & Time	11 AUG 2020 13:08
PC Close Date & Time	11 AUG 2020 15:38

FDA-CBER-2022-1614-0507588

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ● Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ●
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ●
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ● Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	11 AUG 2020 20:00
PC Open Date & Time	11 AUG 2020 16:33
PC Close Date & Time	12 AUG 2020 11:59

FDA-CBER-2022-1614-0507589

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 2
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	12 AUG 2020 14:40
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

FDA-CBER-2022-1614-0507590

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:08:42

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	13 AUG 2020 22:28
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 4
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ☐ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ☐
Please record - **REDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site redness with the ruler provided.	
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ☐
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site swelling/hardness with the ruler provided.	
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ☐ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

FDA-CBER-2022-1614-0507592

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:08:42

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	15 AUG 2020 16:27
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

FDA-CBER-2022-1614-0507593

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:08:42

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	17 AUG 2020 09:23
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

FDA-CBER-2022-1614-0507594

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:08:42

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	18 AUG 2020 11:07
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

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

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:08:42

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	11 AUG 2020 13:23
PC Open Date & Time	11 AUG 2020 13:08
PC Close Date & Time	11 AUG 2020 15:38

FDA-CBER-2022-1614-0507597

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

FDA-CBER-2022-1614-0507598

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:08:42

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	11 AUG 2020 20:02
PC Open Date & Time	11 AUG 2020 16:33
PC Close Date & Time	12 AUG 2020 11:59

FDA-CBER-2022-1614-0507599

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:08:42

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-2022-1614-0507600

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:08:42

	Yes ☐
PC Time stamp	12 AUG 2020 14:41
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

FDA-CBER-2022-1614-0507601

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 3
HEADACHE	None ■
	No interference with activity ☐
	Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ☐
	Any use of prescription pain reliever or prevents daily activity ☐
FATIGUE	None ☐
	No interference with activity ■
	Some interference with activity ☐
	Significant; prevents daily activity ☐
MUSCLE ACHES ALL OVER BODY	None ☐
	No interference with activity ■
	Some interference with activity ☐
	Significant; prevents daily activity ☐
JOINT ACHES IN SEVERAL JOINTS	None ■
	No interference with activity ☐
	Some interference with activity ☐
	Significant; prevents daily activity ☐
NAUSEA/VOMITING	None ■
	No interference with activity or 1-2 episodes/24 hours ☐
	Some interference with activity or >2 episodes/24 hours ☐
	Prevents daily activity, requires outpatient IV hydration ☐
CHILLS	None ■
	No interference with activity ☐
	Some interference with activity not requiring medical attention ☐
	Prevents daily activity and requires medical attention ☐
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■

FDA-CBER-2022-1614-0507602

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:08:42

	Yes ☐
PC Time stamp	13 AUG 2020 22:29
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

FDA-CBER-2022-1614-0507603

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 4
HEADACHE	None ☐
	No interference with activity ☐
	Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ☐
	Any use of prescription pain reliever or prevents daily activity ☐
FATIGUE	None ☐
	No interference with activity ☐
	Some interference with activity ☐
	Significant; prevents daily activity ☐
MUSCLE ACHES ALL OVER BODY	None ☐
	No interference with activity ☐
	Some interference with activity ☐
	Significant; prevents daily activity ☐
JOINT ACHES IN SEVERAL JOINTS	None ☐
	No interference with activity ☐
	Some interference with activity ☐
	Significant; prevents daily activity ☐
NAUSEA/VOMITING	None ☐
	No interference with activity or 1-2 episodes/24 hours ☐
	Some interference with activity or >2 episodes/24 hours ☐
	Prevents daily activity, requires outpatient IV hydration ☐
CHILLS	None ☐
	No interference with activity ☐
	Some interference with activity not requiring medical attention ☐
	Prevents daily activity and requires medical attention ☐
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☐

FDA-CBER-2022-1614-0507604

	Yes ☐
PC Time stamp	
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 5
HEADACHE	None ■
	No interference with activity ☐
	Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ☐
	Any use of prescription pain reliever or prevents daily activity ☐
FATIGUE	None ■
	No interference with activity ☐
	Some interference with activity ☐
	Significant; prevents daily activity ☐
MUSCLE ACHES ALL OVER BODY	None ☐
	No interference with activity ■
	Some interference with activity ☐
	Significant; prevents daily activity ☐
JOINT ACHES IN SEVERAL JOINTS	None ☐
	No interference with activity ■
	Some interference with activity ☐
	Significant; prevents daily activity ☐
NAUSEA/VOMITING	None ■
	No interference with activity or 1-2 episodes/24 hours ☐
	Some interference with activity or >2 episodes/24 hours ☐
	Prevents daily activity, requires outpatient IV hydration ☐
CHILLS	None ■
	No interference with activity ☐
	Some interference with activity not requiring medical attention ☐
	Prevents daily activity and requires medical attention ☐
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■

FDA-CBER-2022-1614-0507606

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:08:42

	Yes ☐
PC Time stamp	15 AUG 2020 16:28
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

FDA-CBER-2022-1614-0507607

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:08:42

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-2022-1614-0507608

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:08:42

	Yes ☐
PC Time stamp	17 AUG 2020 09:25
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

FDA-CBER-2022-1614-0507609

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:08:42

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-2022-1614-0507610

	Yes ☐
PC Time stamp	18 AUG 2020 11:08
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3112192
Folder: Diary Dose 1 (1)
Form: Headache_Day(8)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 8
Select one response below to indicate the intensity of your **HEADACHE**	None ☑ No interference with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or some interfererence with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	19 AUG 2020 09:49
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

FDA-CBER-2022-1614-0507612

US3112192
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(8)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 8
Select one response below to indicate the intensity of your **FATIGUE**	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
PC Time Stamp	19 AUG 2020 09:49
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

FDA-CBER-2022-1614-0507613

US3112192
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 8
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	19 AUG 2020 09:49
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3112192
Folder: Safety Call Day 8 (1)
Form: Safety Call
Data signed: (b) (4) **12 Feb 2021 21:42:50**
Generated On: 09 Jun 2021 15:08:42

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	19 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-2022-1614-0507615

US3112192
Folder: Safety Call Day 8 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 21:42:50**
Generated On: 09 Jun 2021 15:08:42

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

FDA-CBER-2022-1614-0507616

US3112192
Folder: Safety Call Day 15 (1)
Form: Safety Call
Data signed: (b) (4) **12 Feb 2021 21:42:27**
Generated On: 09 Jun 2021 15:08:42

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

US3112192
Folder: Safety Call Day 15 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 21:42:27**
Generated On: 09 Jun 2021 15:08:42

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

FDA-CBER-2022-1614-0507618

US3112192
Folder: Safety Call Day 22 (1)
Form: Safety Call
Data signed: (b) (4) **12 Feb 2021 21:42:27**
Generated On: 09 Jun 2021 15:08:42

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	01 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-2022-1614-0507619

US3112192
Folder: Safety Call Day 22 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 21:42:27**
Generated On: 09 Jun 2021 15:08:42

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

FDA-CBER-2022-1614-0507620

US3112192
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Data signed: (b) (4) **12 Feb 2021 21:01:30**
Generated On: 09 Jun 2021 15:08:42

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	11 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT2

FDA-CBER-2022-1614-0507621

US3112192
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **12 Feb 2021 21:01:30**
Generated On: 09 Jun 2021 15:08:42

Timepoint	Pre-Dose ■ Post-Dose ☐
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	11 SEP 2020
Time of assessment *(00:00-23:59)*	09:13 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 09:13
Temperature *(xxx.x)*	99.3 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	49 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	66 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-0507622

US3112192
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **12 Feb 2021 21:01:30**
Generated On: 09 Jun 2021 15:08:42

Timepoint	Pre-Dose ☐ Post-Dose ■
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	11 SEP 2020
Time of assessment *(00:00-23:59)*	11:20 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 11:20
Temperature *(xxx.x)*	98.3 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	60 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	66 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-0507623

US3112192
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Data signed: (b) (4) **12 Feb 2021 21:01:30**
Generated On: 09 Jun 2021 15:08:42

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	11 SEP 2020

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

FDA-CBER-2022-1614-0507624

US3112192
Folder: Visit 2 Day 29 (1)
Form: Exposure
Data signed: (b) (4) **12 Feb 2021 21:01:30**
Generated On: 09 Jun 2021 15:08:42

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)*	11 SEP 2020
What was the treatment time? *(00:00-23:59)*	10:44 (24 HR)
Treatment Date and Time (derived)	11 SEP 2020 10:44
Which arm was used to give treatment?	Left Arm ☐ Right Arm ■
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

FDA-CBER-2022-1614-0507625

US3112192
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **12 Feb 2021 21:01:30**
Generated On: 09 Jun 2021 15:08:42

Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	11 SEP 2020
Collection time *(00:00-23:59)*	09:50 (24 HR)
Collection date and time (derived)	11 SEP 2020 09:50

FDA-CBER-2022-1614-0507626

US3112192
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **12 Feb 2021 21:01:30**
Generated On: 09 Jun 2021 15:08:42

Collection date *(dd MMM yyyy)*			11 SEP 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:37	11 SEP 2020 09:37
Nasopharyngeal Swab 2	No		

FDA-CBER-2022-1614-0507627

US3112192
Folder: Visit 2 Day 29 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 21:01:30**
Generated On: 09 Jun 2021 15:08:42

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

FDA-CBER-2022-1614-0507628

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:08:42

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.3 °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	11 SEP 2020 11:34
PC Open Date & Time	11 SEP 2020 11:04
PC Close Date & Time	11 SEP 2020 13:34

FDA-CBER-2022-1614-0507629

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ☐ No ☐
Please record your **TEMPERATURE in °F**	
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	
To **PREVENT** pain or fever from occurring	
PC Time Stamp	
PC Open Date & Time	11 SEP 2020 14:29
PC Close Date & Time	12 SEP 2020 11:59

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:08:42

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):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	12 SEP 2020 21:50
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

FDA-CBER-2022-1614-0507631

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 3

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	99.1 °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):	
To **TREAT** pain or fever that has already occurred	False
To **PREVENT** pain or fever from occurring	True
PC Time Stamp	13 SEP 2020 23:20
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

FDA-CBER-2022-1614-0507632

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:08:42

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**	99.6 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ■ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	False
To **PREVENT** pain or fever from occurring	True
PC Time Stamp	15 SEP 2020 08:32
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

FDA-CBER-2022-1614-0507633

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 5

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	99.3 °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):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	15 SEP 2020 13:46
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

FDA-CBER-2022-1614-0507634

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:08:42

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**	99.1 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ■ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	16 SEP 2020 15:25
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

FDA-CBER-2022-1614-0507635

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:08:42

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**	99.3 °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):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	17 SEP 2020 12:52
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

FDA-CBER-2022-1614-0507636

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(8)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 8

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.3 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ■ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	19 SEP 2020 00:59
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

FDA-CBER-2022-1614-0507637

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(9)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 9

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):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	19 SEP 2020 18:56
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

FDA-CBER-2022-1614-0507638

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(10)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 10

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.3 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ■ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	20 SEP 2020 21:39
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

FDA-CBER-2022-1614-0507639

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(11)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 11

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ☐ No ☐
Please record your **TEMPERATURE in °F**	
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	
To **PREVENT** pain or fever from occurring	
PC Time Stamp	
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

FDA-CBER-2022-1614-0507640

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(12)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 12

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.6 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ■ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	23 SEP 2020 09:12
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

FDA-CBER-2022-1614-0507641

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(13)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 13

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ☐ No ☐
Please record your **TEMPERATURE in °F**	
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	
To **PREVENT** pain or fever from occurring	
PC Time Stamp	
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

FDA-CBER-2022-1614-0507642

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(14)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 14

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):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	24 SEP 2020 18:27
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

FDA-CBER-2022-1614-0507643

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(15)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 15

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):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	25 SEP 2020 22:27
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

FDA-CBER-2022-1614-0507644

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(16)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 16

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	99.0 °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):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	26 SEP 2020 18:15
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

FDA-CBER-2022-1614-0507645

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(17)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 17

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	27 SEP 2020 13:27
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

FDA-CBER-2022-1614-0507646

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 1, 30 MINUTES AFTER VACCINATION (AT STUDY CLINIC)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ● Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ●
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ●
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ● Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	11 SEP 2020 11:35
PC Open Date & Time	11 SEP 2020 11:04
PC Close Date & Time	11 SEP 2020 13:34

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ☐ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ☐
Please record - **REDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site redness with the ruler provided.	
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ☐
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site swelling/hardness with the ruler provided.	
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ☐ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	
PC Open Date & Time	11 SEP 2020 14:29
PC Close Date & Time	12 SEP 2020 11:59

FDA-CBER-2022-1614-0507648

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 2
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ☐ Does not interfere with activity ■ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	12 SEP 2020 21:51
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

FDA-CBER-2022-1614-0507649

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 3
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ☐ Does not interfere with activity ■ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ■ No ☐
Please record - **REDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site redness with the ruler provided.	8
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	13 SEP 2020 23:22
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

FDA-CBER-2022-1614-0507650

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:08:42

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	15 SEP 2020 08:33
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

FDA-CBER-2022-1614-0507651

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:08:42

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	15 SEP 2020 13:44
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:08:42

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	16 SEP 2020 15:27
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

FDA-CBER-2022-1614-0507653

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:08:42

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	17 SEP 2020 12:53
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

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

FDA-CBER-2022-1614-0507655

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:08:42

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	11 SEP 2020 11:36
PC Open Date & Time	11 SEP 2020 11:04
PC Close Date & Time	11 SEP 2020 13:34

FDA-CBER-2022-1614-0507656

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

FDA-CBER-2022-1614-0507657

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:08:42

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☐ Yes ☐
PC Time stamp	
PC Open Date & Time	11 SEP 2020 14:29
PC Close Date & Time	12 SEP 2020 11:59

FDA-CBER-2022-1614-0507658

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:08:42

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-2022-1614-0507659

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:08:42

	Yes ☐
PC Time stamp	12 SEP 2020 21:52
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 3
HEADACHE	None ☐
	No interference with activity ■
	Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ☐
	Any use of prescription pain reliever or prevents daily activity ☐
FATIGUE	None ☐
	No interference with activity ☐
	Some interference with activity ■
	Significant; prevents daily activity ☐
MUSCLE ACHES ALL OVER BODY	None ☐
	No interference with activity ☐
	Some interference with activity ■
	Significant; prevents daily activity ☐
JOINT ACHES IN SEVERAL JOINTS	None ☐
	No interference with activity ☐
	Some interference with activity ■
	Significant; prevents daily activity ☐
NAUSEA/VOMITING	None ■
	No interference with activity or 1-2 episodes/24 hours ☐
	Some interference with activity or >2 episodes/24 hours ☐
	Prevents daily activity, requires outpatient IV hydration ☐
CHILLS	None ☐
	No interference with activity ■
	Some interference with activity not requiring medical attention ☐
	Prevents daily activity and requires medical attention ☐
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■

FDA-CBER-2022-1614-0507661

	Yes ☐
PC Time stamp	13 SEP 2020 23:23
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 4
HEADACHE	None ☐
	No interference with activity ■
	Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ☐
	Any use of prescription pain reliever or prevents daily activity ☐
FATIGUE	None ☐
	No interference with activity ☐
	Some interference with activity ■
	Significant; prevents daily activity ☐
MUSCLE ACHES ALL OVER BODY	None ☐
	No interference with activity ☐
	Some interference with activity ■
	Significant; prevents daily activity ☐
JOINT ACHES IN SEVERAL JOINTS	None ☐
	No interference with activity ☐
	Some interference with activity ■
	Significant; prevents daily activity ☐
NAUSEA/VOMITING	None ■
	No interference with activity or 1-2 episodes/24 hours ☐
	Some interference with activity or >2 episodes/24 hours ☐
	Prevents daily activity, requires outpatient IV hydration ☐
CHILLS	None ■
	No interference with activity ☐
	Some interference with activity not requiring medical attention ☐
	Prevents daily activity and requires medical attention ☐
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■

FDA-CBER-2022-1614-0507663

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:08:42

	Yes ☐
PC Time stamp	15 SEP 2020 08:34
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

FDA-CBER-2022-1614-0507664

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 5
HEADACHE	None ■
	No interference with activity ☐
	Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity ☐
	Any use of prescription pain reliever or prevents daily activity ☐
FATIGUE	None ☐
	No interference with activity ☐
	Some interference with activity ■
	Significant; prevents daily activity ☐
MUSCLE ACHES ALL OVER BODY	None ☐
	No interference with activity ☐
	Some interference with activity ■
	Significant; prevents daily activity ☐
JOINT ACHES IN SEVERAL JOINTS	None ☐
	No interference with activity ☐
	Some interference with activity ■
	Significant; prevents daily activity ☐
NAUSEA/VOMITING	None ■
	No interference with activity or 1-2 episodes/24 hours ☐
	Some interference with activity or >2 episodes/24 hours ☐
	Prevents daily activity, requires outpatient IV hydration ☐
CHILLS	None ■
	No interference with activity ☐
	Some interference with activity not requiring medical attention ☐
	Prevents daily activity and requires medical attention ☐
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■

FDA-CBER-2022-1614-0507665

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:08:42

	Yes ☐
PC Time stamp	15 SEP 2020 13:43
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:08:42

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-2022-1614-0507667

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:08:42

	Yes ☐
PC Time stamp	16 SEP 2020 15:26
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:08:42

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-2022-1614-0507669

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:08:42

	Yes ☐
PC Time stamp	17 SEP 2020 12:54
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(8)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 8
Select one response below to indicate the intensity of your **FATIGUE**	None ☐ No interference with activity ■ Some interference with activity ☐ Significant; prevents daily activity ☐
PC Time Stamp	19 SEP 2020 00:59
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

FDA-CBER-2022-1614-0507671

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(9)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 9
Select one response below to indicate the intensity of your **FATIGUE**	None ☐ No interference with activity ☐ Some interference with activity ■ Significant; prevents daily activity ☐
PC Time Stamp	19 SEP 2020 18:56
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

FDA-CBER-2022-1614-0507672

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(10)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 10
Select one response below to indicate the intensity of your **FATIGUE**	None ☐ No interference with activity ■ Some interference with activity ☐ Significant; prevents daily activity ☐
PC Time Stamp	20 SEP 2020 21:44
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

FDA-CBER-2022-1614-0507673

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(11)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 11
Select one response below to indicate the intensity of your **FATIGUE**	None ☐ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
PC Time Stamp	
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

FDA-CBER-2022-1614-0507674

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(12)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 12
Select one response below to indicate the intensity of your **FATIGUE**	None ☐ No interference with activity ■ Some interference with activity ☐ Significant; prevents daily activity ☐
PC Time Stamp	23 SEP 2020 09:12
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

FDA-CBER-2022-1614-0507675

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(13)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 13
Select one response below to indicate the intensity of your **FATIGUE**	None ☐ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
PC Time Stamp	
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

FDA-CBER-2022-1614-0507676

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(14)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 14
Select one response below to indicate the intensity of your **FATIGUE**	None ☐ No interference with activity ■ Some interference with activity ☐ Significant; prevents daily activity ☐
PC Time Stamp	24 SEP 2020 18:25
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

FDA-CBER-2022-1614-0507677

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(15)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 15
Select one response below to indicate the intensity of your **FATIGUE**	None ☐ No interference with activity ■ Some interference with activity ☐ Significant; prevents daily activity ☐
PC Time Stamp	25 SEP 2020 22:28
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

FDA-CBER-2022-1614-0507678

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(16)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 16
Select one response below to indicate the intensity of your **FATIGUE**	None ☐ No interference with activity ■ Some interference with activity ☐ Significant; prevents daily activity ☐
PC Time Stamp	26 SEP 2020 18:16
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

FDA-CBER-2022-1614-0507679

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(17)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 17
Select one response below to indicate the intensity of your **FATIGUE**	None ☐ No interference with activity ☐ Some interference with activity ■ Significant; prevents daily activity ☐
PC Time Stamp	27 SEP 2020 13:28
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

FDA-CBER-2022-1614-0507680

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(18)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 18
Select one response below to indicate the intensity of your **FATIGUE**	None ☐ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
PC Time Stamp	
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

FDA-CBER-2022-1614-0507681

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(19)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 19
Select one response below to indicate the intensity of your **FATIGUE**	None ☐ No interference with activity ■ Some interference with activity ☐ Significant; prevents daily activity ☐
PC Time Stamp	29 SEP 2020 23:14
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

FDA-CBER-2022-1614-0507682

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(20)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 20
Select one response below to indicate the intensity of your **FATIGUE**	None ☐ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
PC Time Stamp	
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

FDA-CBER-2022-1614-0507683

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(21)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 21
Select one response below to indicate the intensity of your **FATIGUE**	None ■ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
PC Time Stamp	01 OCT 2020 21:15
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

FDA-CBER-2022-1614-0507684

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(8)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 8
Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**	None ☐ No interference with activity ☐ Some interference with activity ■ Significant; prevents daily activity ☐
PC Time stamp	19 SEP 2020 01:00
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

FDA-CBER-2022-1614-0507685

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(9)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 9
Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**	None ☐ No interference with activity ☐ Some interference with activity ■ Significant; prevents daily activity ☐
PC Time stamp	19 SEP 2020 18:57
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

FDA-CBER-2022-1614-0507686

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(10)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 10
Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**	None ☐ No interference with activity ■ Some interference with activity ☐ Significant; prevents daily activity ☐
PC Time stamp	20 SEP 2020 21:45
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

FDA-CBER-2022-1614-0507687

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(11)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 11
Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**	None ☐ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
PC Time stamp	
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

FDA-CBER-2022-1614-0507688

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(12)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 12
Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**	None ☐ No interference with activity ■ Some interference with activity ☐ Significant; prevents daily activity ☐
PC Time stamp	23 SEP 2020 09:12
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

FDA-CBER-2022-1614-0507689

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(13)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 13
Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**	None ☐ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
PC Time stamp	
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

FDA-CBER-2022-1614-0507690

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(14)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 14
Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**	None ☐ No interference with activity ■ Some interference with activity ☐ Significant; prevents daily activity ☐
PC Time stamp	24 SEP 2020 18:26
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

FDA-CBER-2022-1614-0507691

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(15)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 15
Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**	None ☐ No interference with activity ☐ Some interference with activity ■ Significant; prevents daily activity ☐
PC Time stamp	25 SEP 2020 22:28
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

FDA-CBER-2022-1614-0507692

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(16)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 16
Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**	None ☐ No interference with activity ☐ Some interference with activity ■ Significant; prevents daily activity ☐
PC Time stamp	26 SEP 2020 18:16
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

FDA-CBER-2022-1614-0507693

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(17)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 17
Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**	None ☐ No interference with activity ☐ Some interference with activity ■ Significant; prevents daily activity ☐
PC Time stamp	27 SEP 2020 13:28
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

FDA-CBER-2022-1614-0507694

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(18)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 18
Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**	None ☐ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
PC Time stamp	
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

FDA-CBER-2022-1614-0507695

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(19)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 19
Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**	None ☐ No interference with activity ■ Some interference with activity ☐ Significant; prevents daily activity ☐
PC Time stamp	29 SEP 2020 23:14
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

FDA-CBER-2022-1614-0507696

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(20)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 20
Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**	None ☐ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
PC Time stamp	
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

FDA-CBER-2022-1614-0507697

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(21)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 21
Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**	None ☐ No interference with activity ■ Some interference with activity ☐ Significant; prevents daily activity ☐
PC Time stamp	01 OCT 2020 21:15
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

FDA-CBER-2022-1614-0507698

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(22)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 22
Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**	None ☐ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
PC Time stamp	
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

FDA-CBER-2022-1614-0507699

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(23)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 23
Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**	None ☐ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
PC Time stamp	
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

FDA-CBER-2022-1614-0507700

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(8)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 8
Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**	None ☐ No interference with activity ☐ Some interference with activity ■ Significant; prevents daily activity ☐
PC Time stamp	19 SEP 2020 01:00
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

FDA-CBER-2022-1614-0507701

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(9)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 9
Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**	None ☐ No interference with activity ■ Some interference with activity ☐ Significant; prevents daily activity ☐
PC Time stamp	19 SEP 2020 18:57
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

FDA-CBER-2022-1614-0507702

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(10)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 10
Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**	None ☐ No interference with activity ☐ Some interference with activity ■ Significant; prevents daily activity ☐
PC Time stamp	20 SEP 2020 21:47
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

FDA-CBER-2022-1614-0507703

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(11)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 11
Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**	None ☐ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
PC Time stamp	
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

FDA-CBER-2022-1614-0507704

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(12)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 12
Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**	None ☐ No interference with activity ■ Some interference with activity ☐ Significant; prevents daily activity ☐
PC Time stamp	23 SEP 2020 09:12
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

FDA-CBER-2022-1614-0507705

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(13)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 13
Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**	None ☐ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
PC Time stamp	
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

FDA-CBER-2022-1614-0507706

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(14)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 14
Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**	None ☐ No interference with activity ☐ Some interference with activity ■ Significant; prevents daily activity ☐
PC Time stamp	24 SEP 2020 18:25
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

FDA-CBER-2022-1614-0507707

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(15)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 15
Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**	None ☐ No interference with activity ☐ Some interference with activity ■ Significant; prevents daily activity ☐
PC Time stamp	25 SEP 2020 22:28
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

FDA-CBER-2022-1614-0507708

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(16)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 16
Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**	None ☐ No interference with activity ■ Some interference with activity ☐ Significant; prevents daily activity ☐
PC Time stamp	26 SEP 2020 18:16
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

FDA-CBER-2022-1614-0507709

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(17)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 17
Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**	None ☐ No interference with activity ☐ Some interference with activity ■ Significant; prevents daily activity ☐
PC Time stamp	27 SEP 2020 13:28
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

FDA-CBER-2022-1614-0507710

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(18)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 18
Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**	None ☐ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
PC Time stamp	
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

FDA-CBER-2022-1614-0507711

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(19)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 19
Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**	None ☐ No interference with activity ■ Some interference with activity ☐ Significant; prevents daily activity ☐
PC Time stamp	29 SEP 2020 23:14
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

FDA-CBER-2022-1614-0507712

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(20)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 20
Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**	None ☐ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
PC Time stamp	
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

FDA-CBER-2022-1614-0507713

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(21)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 21
Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**	None ☐ No interference with activity ■ Some interference with activity ☐ Significant; prevents daily activity ☐
PC Time stamp	01 OCT 2020 21:15
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

FDA-CBER-2022-1614-0507714

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(22)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 22
Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**	None ☐ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
PC Time stamp	
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

FDA-CBER-2022-1614-0507715

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(23)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 23
Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**	None ☐ No interference with activity ☐ Some interference with activity ☐ Significant; prevents daily activity ☐
PC Time stamp	
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

FDA-CBER-2022-1614-0507716

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(8)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 8
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☐ Yes ■
PC Time stamp	19 SEP 2020 01:01
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

FDA-CBER-2022-1614-0507717

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(9)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 9
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	19 SEP 2020 18:57
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(10)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 10
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	20 SEP 2020 21:47
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(11)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 11
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☐ Yes ☐
PC Time stamp	
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

FDA-CBER-2022-1614-0507720

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(12)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 12
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	23 SEP 2020 09:12
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(13)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 13
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☐ Yes ☐
PC Time stamp	
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(14)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 14
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	24 SEP 2020 18:25
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(15)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 15
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	25 SEP 2020 22:28
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(16)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 16
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	26 SEP 2020 18:17
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(17)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 17
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	27 SEP 2020 13:28
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

FDA-CBER-2022-1614-0507726

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(18)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 18
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☐ Yes ☐
PC Time stamp	
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

FDA-CBER-2022-1614-0507727

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(19)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 19
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☐ Yes ■
PC Time stamp	29 SEP 2020 23:15
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

FDA-CBER-2022-1614-0507728

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(20)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 20
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☐ Yes ☐
PC Time stamp	
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

FDA-CBER-2022-1614-0507729

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(21)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 21
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	01 OCT 2020 21:15
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(22)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 22
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☐ Yes ☐
PC Time stamp	
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

FDA-CBER-2022-1614-0507731

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(23)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 23
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☐ Yes ☐
PC Time stamp	
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

FDA-CBER-2022-1614-0507732

US3112192
Folder: Diary Dose 2 (1)
Form: Underarm Gland_Day(8)
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 8
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	19 SEP 2020 01:02
PC Open Date and Time	18 SEP 2020 12:00
PC Close Date and Time	19 SEP 2020 11:59

FDA-CBER-2022-1614-0507733

US3112192
Folder: Safety Call Day 36 (1)
Form: Safety Call
Data signed: (b) (4) **12 Feb 2021 21:42:50**
Generated On: 09 Jun 2021 15:08:42

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	18 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-2022-1614-0507734

US3112192
Folder: Safety Call Day 36 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 21:42:50**
Generated On: 09 Jun 2021 15:08:42

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

FDA-CBER-2022-1614-0507735

US3112192
Folder: Safety Call Day 43 (1)
Form: Safety Call
Data signed: (b) (4) **12 Feb 2021 21:01:30**
Generated On: 09 Jun 2021 15:08:42

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	25 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-2022-1614-0507736

US3112192
Folder: Safety Call Day 43 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 21:01:30**
Generated On: 09 Jun 2021 15:08:42

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

FDA-CBER-2022-1614-0507737

US3112192
Folder: Safety Call Day 50 (1)
Form: Safety Call
Data signed: (b) (4) **12 Feb 2021 21:01:30**
Generated On: 09 Jun 2021 15:08:42

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	5 OCT 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

FDA-CBER-2022-1614-0507738

US3112192
Folder: Safety Call Day 50 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 21:01:30**
Generated On: 09 Jun 2021 15:08:42

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

FDA-CBER-2022-1614-0507739

US3112192
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Data signed: (b) (4) **12 Feb 2021 21:01:30**
Generated On: 09 Jun 2021 15:08:42

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	9 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT3

FDA-CBER-2022-1614-0507740

US3112192
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Data signed: (b) (4) **12 Feb 2021 21:01:30**
Generated On: 09 Jun 2021 15:08:42

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	9 OCT 2020
Time of assessment *(00:00-23:59)*	10:21 (24 HR)
Vital Signs Date and Time (derived)	9 OCT 2020 10:21
Temperature *(xxx.x)*	98.6 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	56 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3112192
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Data signed: (b) (4) **12 Feb 2021 21:01:30**
Generated On: 09 Jun 2021 15:08:42

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.

US3112192
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **12 Feb 2021 21:01:30**
Generated On: 09 Jun 2021 15:08:42

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	9 OCT 2020
Collection time *(00:00-23:59)*	10:50 (24 HR)
Collection date and time (derived)	9 OCT 2020 10:50

FDA-CBER-2022-1614-0507743

US3112192
Folder: Visit 3 Day 57 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 21:01:30**
Generated On: 09 Jun 2021 15:08:42

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

FDA-CBER-2022-1614-0507744

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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	11 OCT 2020 00:01
Patient Cloud Close Date & Time	15 OCT 2020 23:59

FDA-CBER-2022-1614-0507746

US3112192
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

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 ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ■
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ■
Date and time of submission	20 OCT 2020 23:18:42
Patient Cloud Open Date & Time	18 OCT 2020 00:01
Patient Cloud Close Date & Time	22 OCT 2020 23:59

FDA-CBER-2022-1614-0507747

US3112192
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 OCT 2020 23:19:11
Patient Cloud Open Date & Time	25 OCT 2020 00:01
Patient Cloud Close Date & Time	29 OCT 2020 23:59

FDA-CBER-2022-1614-0507748

US3112192
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ■
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Date and time of submission	08 NOV 2020 20:43:33
Patient Cloud Open Date & Time	08 NOV 2020 00:01
Patient Cloud Close Date & Time	12 NOV 2020 23:59

FDA-CBER-2022-1614-0507749

US3112192
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 NOV 2020 18:44:58
Patient Cloud Open Date & Time	15 NOV 2020 00:01
Patient Cloud Close Date & Time	19 NOV 2020 23:59

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 NOV 2020 12:46:20
Patient Cloud Open Date & Time	19 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

FDA-CBER-2022-1614-0507751

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 NOV 2020 11:09:13
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

FDA-CBER-2022-1614-0507752

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 DEC 2020 23:16:23
Patient Cloud Open Date & Time	03 DEC 2020 00:01
Patient Cloud Close Date & Time	07 DEC 2020 23:59

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 DEC 2020 22:18:08
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 DEC 2020 21:53:06
Patient Cloud Open Date & Time	17 DEC 2020 00:01
Patient Cloud Close Date & Time	21 DEC 2020 23:59

FDA-CBER-2022-1614-0507755

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 DEC 2020 17:41:41
Patient Cloud Open Date & Time	24 DEC 2020 00:01
Patient Cloud Close Date & Time	28 DEC 2020 23:59

FDA-CBER-2022-1614-0507756

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 JAN 2021 22:03:13
Patient Cloud Open Date & Time	31 DEC 2020 00:01
Patient Cloud Close Date & Time	04 JAN 2021 23:59

FDA-CBER-2022-1614-0507757

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-0507758

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

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

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 JAN 2021 07:40:25
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 JAN 2021 21:15:11
Patient Cloud Open Date & Time	21 JAN 2021 00:01
Patient Cloud Close Date & Time	25 JAN 2021 23:59

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	31 JAN 2021 23:10:00
Patient Cloud Open Date & Time	28 JAN 2021 00:01
Patient Cloud Close Date & Time	01 FEB 2021 23:59

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this 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 ☐

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

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

FDA-CBER-2022-1614-0507764

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this 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 ☐

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

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

FDA-CBER-2022-1614-0507766

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

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

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 MAR 2021 19:50:05
Patient Cloud Open Date & Time	25 FEB 2021 00:01
Patient Cloud Close Date & Time	01 MAR 2021 23:59

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 MAR 2021 09:12:42
Patient Cloud Open Date & Time	04 MAR 2021 00:01
Patient Cloud Close Date & Time	08 MAR 2021 23:59

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 MAR 2021 18:16:56
Patient Cloud Open Date & Time	11 MAR 2021 00:01
Patient Cloud Close Date & Time	15 MAR 2021 23:59

FDA-CBER-2022-1614-0507771

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 MAR 2021 10:06:44
Patient Cloud Open Date & Time	18 MAR 2021 00:01
Patient Cloud Close Date & Time	22 MAR 2021 23:59

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this 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 ☐

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

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

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 APR 2021 20:10:19
Patient Cloud Open Date & Time	01 APR 2021 00:01
Patient Cloud Close Date & Time	05 APR 2021 23:59

FDA-CBER-2022-1614-0507775

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ■
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ■
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ■
Date and time of submission	08 APR 2021 18:16:20
Patient Cloud Open Date & Time	08 APR 2021 00:01
Patient Cloud Close Date & Time	12 APR 2021 23:59

FDA-CBER-2022-1614-0507776

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-0507777

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

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 APR 2021 19:33:18
Patient Cloud Open Date & Time	22 APR 2021 00:01
Patient Cloud Close Date & Time	26 APR 2021 23:59

FDA-CBER-2022-1614-0507779

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 APR 2021 23:16:47
Patient Cloud Open Date & Time	29 APR 2021 00:01
Patient Cloud Close Date & Time	03 MAY 2021 23:59

FDA-CBER-2022-1614-0507780

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

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

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

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

FDA-CBER-2022-1614-0507783

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2021 00:01
Patient Cloud Close Date & Time	24 MAY 2021 23:59

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

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2021 00:01
Patient Cloud Close Date & Time	31 MAY 2021 23:59

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

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

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2021 00:01
Patient Cloud Close Date & Time	07 JUN 2021 23:59

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

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2021 00:01
Patient Cloud Close Date & Time	21 JUN 2021 23:59

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

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

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

FDA-CBER-2022-1614-0507796

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

FDA-CBER-2022-1614-0507797

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

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

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

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

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

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

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

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

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

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

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

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	29 JUL 2021 00:01
Patient Cloud Close Date & Time	02 AUG 2021 23:59

FDA-CBER-2022-1614-0507806

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

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

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

FDA-CBER-2022-1614-0507808

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

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	12 AUG 2021 00:01
Patient Cloud Close Date & Time	16 AUG 2021 23:59

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

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

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

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	26 AUG 2021 00:01
Patient Cloud Close Date & Time	30 AUG 2021 23:59

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	02 SEP 2021 00:01
Patient Cloud Close Date & Time	06 SEP 2021 23:59

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	09 SEP 2021 00:01
Patient Cloud Close Date & Time	13 SEP 2021 23:59

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

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	16 SEP 2021 00:01
Patient Cloud Close Date & Time	20 SEP 2021 23:59

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

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

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

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

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

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	30 SEP 2021 00:01
Patient Cloud Close Date & Time	04 OCT 2021 23:59

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

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

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

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

FDA-CBER-2022-1614-0507828

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

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

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

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

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

FDA-CBER-2022-1614-0507832

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

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

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

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

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

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

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

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

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

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	02 DEC 2021 00:01
Patient Cloud Close Date & Time	06 DEC 2021 23:59

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	09 DEC 2021 00:01
Patient Cloud Close Date & Time	13 DEC 2021 23:59

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	16 DEC 2021 00:01
Patient Cloud Close Date & Time	20 DEC 2021 23:59

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

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

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

FDA-CBER-2022-1614-0507848

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

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	30 DEC 2021 00:01
Patient Cloud Close Date & Time	03 JAN 2022 23:59

FDA-CBER-2022-1614-0507850

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	06 JAN 2022 00:01
Patient Cloud Close Date & Time	10 JAN 2022 23:59

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	13 JAN 2022 00:01
Patient Cloud Close Date & Time	17 JAN 2022 23:59

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

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

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

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

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 00:01
Patient Cloud Close Date & Time	31 JAN 2022 23:59

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

FDA-CBER-2022-1614-0507859

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

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

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

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	10 FEB 2022 00:01
Patient Cloud Close Date & Time	14 FEB 2022 23:59

FDA-CBER-2022-1614-0507862

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

FDA-CBER-2022-1614-0507863

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

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

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

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

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

FDA-CBER-2022-1614-0507866

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

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

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

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	10 MAR 2022 00:01
Patient Cloud Close Date & Time	14 MAR 2022 23:59

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

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

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

FDA-CBER-2022-1614-0507872

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

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

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

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

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

FDA-CBER-2022-1614-0507875

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

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

FDA-CBER-2022-1614-0507876

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

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

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

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

FDA-CBER-2022-1614-0507879

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

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

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	21 APR 2022 00:01
Patient Cloud Close Date & Time	25 APR 2022 23:59

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	28 APR 2022 00:01
Patient Cloud Close Date & Time	02 MAY 2022 23:59

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

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

FDA-CBER-2022-1614-0507885

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	05 MAY 2022 00:01
Patient Cloud Close Date & Time	09 MAY 2022 23:59

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

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	12 MAY 2022 00:01
Patient Cloud Close Date & Time	16 MAY 2022 23:59

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

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

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

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

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

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

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	26 MAY 2022 00:01
Patient Cloud Close Date & Time	30 MAY 2022 23:59

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

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	02 JUN 2022 00:01
Patient Cloud Close Date & Time	06 JUN 2022 23:59

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

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	09 JUN 2022 00:01
Patient Cloud Close Date & Time	13 JUN 2022 23:59

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

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	16 JUN 2022 00:01
Patient Cloud Close Date & Time	20 JUN 2022 23:59

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

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	23 JUN 2022 00:01
Patient Cloud Close Date & Time	27 JUN 2022 23:59

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

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	30 JUN 2022 00:01
Patient Cloud Close Date & Time	04 JUL 2022 23:59

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

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

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

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

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

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

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

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	21 JUL 2022 00:01
Patient Cloud Close Date & Time	25 JUL 2022 23:59

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

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

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

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

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

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

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

FDA-CBER-2022-1614-0507913

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

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

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

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

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

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

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

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

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

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

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

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

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

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

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

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

FDA-CBER-2022-1614-0507925

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	22 SEP 2022 00:01
Patient Cloud Close Date & Time	26 SEP 2022 23:59

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

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

FDA-CBER-2022-1614-0507927

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	29 SEP 2022 00:01
Patient Cloud Close Date & Time	03 OCT 2022 23:59

FDA-CBER-2022-1614-0507928

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	06 OCT 2022 00:01
Patient Cloud Close Date & Time	10 OCT 2022 23:59

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

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	13 OCT 2022 00:01
Patient Cloud Close Date & Time	17 OCT 2022 23:59

US3112192
Folder: Cosmetic Injections and Dermal Fillers
Form: Cosmetic Injection_ Dermal Filler eDiary
Generated On: 09 Jun 2021 15:08:42

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 19:50:27

FDA-CBER-2022-1614-0507933

US3112192
Folder: Safety Call Day 85 (1)
Form: Safety Call
Data signed: (b) (4) **05 Mar 2021 19:49:39**
Generated On: 09 Jun 2021 15:08:42

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

FDA-CBER-2022-1614-0507934

US3112192
Folder: Safety Call Day 85 (1)
Form: Continuing
Data signed: (b) (4) **05 Mar 2021 19:49:39**
Generated On: 09 Jun 2021 15:08:42

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

FDA-CBER-2022-1614-0507935

US3112192
Folder: Safety Call Day 119 (1)
Form: Safety Call
Data signed: (b) (4) **02 Apr 2021 21:13:14**
Generated On: 09 Jun 2021 15:08:42

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	10 DEC 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

FDA-CBER-2022-1614-0507936

US3112192
Folder: Safety Call Day 119 (1)
Form: Continuing
Data signed: (b) (4) **02 Apr 2021 21:13:14**
Generated On: 09 Jun 2021 15:08:42

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

FDA-CBER-2022-1614-0507937

US3112192
Folder: Safety Call Day 149 (1)
Form: Safety Call
Data signed: (b) (4) **02 Apr 2021 21:13:15**
Generated On: 09 Jun 2021 15:08:42

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

FDA-CBER-2022-1614-0507938

US3112192
Folder: Safety Call Day 149 (1)
Form: Continuing
Data signed: (b) (4) **02 Apr 2021 21:13:14**
Generated On: 09 Jun 2021 15:08:42

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

FDA-CBER-2022-1614-0507939

US3112192
Folder: Safety Call Day 179 (1)
Form: Safety Call
Data signed: (b) (4) **02 Apr 2021 21:13:15**
Generated On: 09 Jun 2021 15:08:42

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	9 FEB 2021
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

FDA-CBER-2022-1614-0507940

US3112192
Folder: Safety Call Day 179 (1)
Form: Continuing
Data signed: (b) (4) **02 Apr 2021 21:13:15**
Generated On: 09 Jun 2021 15:08:42

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

FDA-CBER-2022-1614-0507941

US3112192
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Data signed: (b) (4) **02 Apr 2021 21:13:15**
Generated On: 09 Jun 2021 15:08:42

Was this visit performed?	Yes ☑ No ☐
Visit date (dd MMM yyyy)	10 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ☑
Folder OID	VISIT4

FDA-CBER-2022-1614-0507942

US3112192
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Data signed: (b) (4) **02 Apr 2021 21:13:15**
Generated On: 09 Jun 2021 15:08:42

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	10 MAR 2021
Time of assessment *(00:00-23:59)*	11:25 (24 HR)
Vital Signs Date and Time (derived)	10 MAR 2021 11:25
Temperature *(xxx.x)*	98.6 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	71 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	65 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3112192
Folder: Visit 4 Day 209 (1)
Form: Physical Examination
Data signed: (b) (4) **02 Apr 2021 21:13:15**
Generated On: 09 Jun 2021 15:08:42

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.

US3112192
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **02 Apr 2021 21:13:15**
Generated On: 09 Jun 2021 15:08:42

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	10 MAR 2021
Collection time *(00:00-23:59)*	11:35 (24 HR)
Collection date and time (derived)	10 MAR 2021 11:35

FDA-CBER-2022-1614-0507945

US3112192
Folder: Visit 4 Day 209 (1)
Form: Continuing
Data signed: (b) (4) **02 Apr 2021 21:13:15**
Generated On: 09 Jun 2021 15:08:42

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

FDA-CBER-2022-1614-0507946

US3112192
Folder: Safety Call Day 239 (1)
Form: Safety Call
Data signed: (b) (4) **15 Apr 2021 23:36:03**
Generated On: 09 Jun 2021 15:08:42

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	9 APR 2021
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

FDA-CBER-2022-1614-0507947

US3112192
Folder: Safety Call Day 239 (1)
Form: Continuing
Data signed: (b) (4) **15 Apr 2021 23:36:03**
Generated On: 09 Jun 2021 15:08:42

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

FDA-CBER-2022-1614-0507948

US3112192
Folder: Safety Call Day 269 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:08:42

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-2022-1614-0507949

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

US3112192
Folder: Covid-19 Assessment (1)
Form: COVID-19 Contact
Generated On: 09 Jun 2021 15:08:42

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-2022-1614-0507951

Generate Next COVID-19 Assessment	Yes ☐ No ☐

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Data signed: (b) (4) **02 Apr 2021 21:13:14**
Generated On: 09 Jun 2021 15:08:42

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	5 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	UNBLND_DECIDE

FDA-CBER-2022-1614-0507953

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Data signed: (b) (4) **09 Apr 2021 00:06:59**
Generated On: 09 Jun 2021 15:08:42

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

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Data signed: (b) (4) **02 Apr 2021 21:13:14**
Generated On: 09 Jun 2021 15:08:42

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

FDA-CBER-2022-1614-0507955

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **02 Apr 2021 21:13:14**
Generated On: 09 Jun 2021 15:08:42

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose ■ Post-Dose ☐
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	5 JAN 2021
Time of assessment *(00:00-23:59)*	11:09 (24 HR)
Vital Signs Date and Time (derived)	5 JAN 2021 11:09
Temperature *(xxx.x)*	99.5 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	52 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	157 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	81 mmHg
Diastolic Blood Pressure units	MMHG

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **02 Apr 2021 21:13:14**
Generated On: 09 Jun 2021 15:08:42

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose ☐ Post-Dose ■
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	5 JAN 2021
Time of assessment *(00:00-23:59)*	12:16 (24 HR)
Vital Signs Date and Time (derived)	5 JAN 2021 12:16
Temperature *(xxx.x)*	98.7 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	60 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	78 mmHg
Diastolic Blood Pressure units	MMHG

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Physical Examination
Data signed: (b) (4) **02 Apr 2021 21:13:14**
Generated On: 09 Jun 2021 15:08:42

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	5 JAN 2021

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

FDA-CBER-2022-1614-0507958

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Data signed: (b) (4) **02 Apr 2021 21:13:14**
Generated On: 09 Jun 2021 15:08:42

Was study treatment given?	Yes ■ No ☐
If No, reason not given	Participant declined due to Adverse Event ☐ Physician withheld dose due to Adverse Event ☐ Death ☐ Lost To Follow-Up ☐ Physician Decision ☐ Pregnancy ☐ Protocol Deviation ☐ Study Terminated by Sponsor ☐ Withdrawal of Consent by Participant ☐ Confirmed COVID-19 ☐ Other ☐
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment? (Unblinded)	MRNA-1273
What was the treatment date? *(dd MMM yyyy)*	5 JAN 2021
What was the treatment time? *(00:00-23:59)*	11:45 (24 HR)
Treatment Date and Time (derived)	5 JAN 2021 11:45
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

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **02 Apr 2021 21:13:14**
Generated On: 09 Jun 2021 15:08:42

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	5 JAN 2021
Collection time *(00:00-23:59)*	11:30 (24 HR)
Collection date and time (derived)	5 JAN 2021 11:30

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Data signed: (b) (4) **02 Apr 2021 21:13:14**
Generated On: 09 Jun 2021 15:08:42

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	5 JAN 2021
Collection time *(00:00 - 23:59)*	11:12
Collection Date and Time (derived)	5 JAN 2021 11:12

FDA-CBER-2022-1614-0507961

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Continuing
Data signed: (b) (4) **02 Apr 2021 21:13:14**
Generated On: 09 Jun 2021 15:08:42

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

US3112192
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Data signed: (b) (4) **02 Apr 2021 21:13:15**
Generated On: 09 Jun 2021 15:08:42

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	12 JAN 2021
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

FDA-CBER-2022-1614-0507963

US3112192
Folder: Safety Call OL-D8 (1)
Form: Continuing
Data signed: (b) (4) **02 Apr 2021 21:13:15**
Generated On: 09 Jun 2021 15:08:42

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

FDA-CBER-2022-1614-0507964

US3112192
Folder: OL-D29 (1)
Form: Visit Date
Data signed: (b) (4) **02 Apr 2021 21:12:52**
Generated On: 09 Jun 2021 15:08:42

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	2 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	OLD29

FDA-CBER-2022-1614-0507965

US3112192
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **02 Apr 2021 21:13:14**
Generated On: 09 Jun 2021 15:08:42

Timepoint	Pre-Dose ■ Post-Dose ☐
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	2 FEB 2021
Time of assessment *(00:00-23:59)*	10:14 (24 HR)
Vital Signs Date and Time (derived)	2 FEB 2021 10:14
Temperature *(xxx.x)*	98.2 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	72 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	60 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-0507966

US3112192
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **02 Apr 2021 21:13:14**
Generated On: 09 Jun 2021 15:08:42

Timepoint	Pre-Dose ☐ Post-Dose ■
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	2 FEB 2021
Time of assessment *(00:00-23:59)*	10:52 (24 HR)
Vital Signs Date and Time (derived)	2 FEB 2021 10:52
Temperature *(xxx.x)*	98.9 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	78 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	62 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-0507967

US3112192
Folder: OL-D29 (1)
Form: Physical Examination
Data signed: (b) (4) **02 Apr 2021 21:12:52**
Generated On: 09 Jun 2021 15:08:42

Was the physical examination performed?	Yes ☑ No ☐
Date of examination *(dd MMM yyyy)*	2 FEB 2021

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

US3112192
Folder: OL-D29 (1)
Form: Exposure
Data signed: (b) (4) **02 Apr 2021 21:12:52**
Generated On: 09 Jun 2021 15:08:42

Was study treatment given?	Yes ■ No ☐
If No, reason not given	Participant declined due to Adverse Event ☐ Physician withheld dose due to Adverse Event ☐ Death ☐ Lost To Follow-Up ☐ Physician Decision ☐ Pregnancy ☐ Protocol Deviation ☐ Study Terminated by Sponsor ☐ Withdrawal of Consent by Participant ☐ Confirmed COVID-19 ☐ Other ☐
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment? (Unblinded)	MRNA-1273
What was the treatment date? *(dd MMM yyyy)*	2 FEB 2021
What was the treatment time? *(00:00-23:59)*	10:21 (24 HR)
Treatment Date and Time (derived)	2 FEB 2021 10:21
Which arm was used to give treatment?	Left Arm ☐ Right Arm ■
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

US3112192
Folder: OL-D29 (1)
Form: Continuing
Data signed: (b) (4) **02 Apr 2021 21:12:52**
Generated On: 09 Jun 2021 15:08:42

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

FDA-CBER-2022-1614-0507970

US3112192
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Data signed: (b) (4) **02 Apr 2021 21:13:15**
Generated On: 09 Jun 2021 15:08:42

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	9 FEB 2021
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

FDA-CBER-2022-1614-0507971

US3112192
Folder: Safety Call OL-D36 (1)
Form: Continuing
Data signed: (b) (4) **02 Apr 2021 21:13:15**
Generated On: 09 Jun 2021 15:08:42

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

FDA-CBER-2022-1614-0507972

US3112192
Folder: OL-D57 (1)
Form: Visit Date
Data signed: (b) (4) **02 Apr 2021 21:13:14**
Generated On: 09 Jun 2021 15:08:42

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	10 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	OLD57

FDA-CBER-2022-1614-0507973

US3112192
Folder: OL-D57 (1)
Form: Vital Signs
Data signed: (b) (4) **02 Apr 2021 21:13:14**
Generated On: 09 Jun 2021 15:08:42

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	10 MAR 2021
Time of assessment *(00:00-23:59)*	11:25 (24 HR)
Vital Signs Date and Time (derived)	10 MAR 2021 11:25
Temperature *(xxx.x)*	98.6 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	71 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	65 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3112192
Folder: OL-D57 (1)
Form: Physical Examination
Data signed: (b) (4) **02 Apr 2021 21:13:14**
Generated On: 09 Jun 2021 15:08:42

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	10 MAR 2021

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

FDA-CBER-2022-1614-0507975

US3112192
Folder: OL-D57 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **02 Apr 2021 21:13:14**
Generated On: 09 Jun 2021 15:08:42

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	10 MAR 2021
Collection time *(00:00-23:59)*	11:35 (24 HR)
Collection date and time (derived)	10 MAR 2021 11:35

FDA-CBER-2022-1614-0507976

US3112192
Folder: Adverse Events
Form: Adverse Events Summary
Data signed: (b) (4) **19 Mar 2021 20:24:11**
Generated On: 09 Jun 2021 15:08:42

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

If Yes, enter details on the Adverse Events form.

FDA-CBER-2022-1614-0507977

US3112192
Folder: Adverse Events
Form: Adverse Events (1)
Data signed: (b) (4) **19 Mar 2021 20:24:11**
Generated On: 09 Jun 2021 15:08:42

AEID	
Adverse event	LEFT KNEE CONTUSION
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)*	1 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)*	16 SEP 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ■ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ■
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	

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

US3112192
Folder: Adverse Events
Form: Adverse Events (2)
Data signed: (b) (4) **19 Mar 2021 20:24:11**
Generated On: 09 Jun 2021 15:08:42

AEID	
Adverse event	LEFT SHOULDER CONTUSION
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)*	1 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)*	21 SEP 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ■ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ■
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	

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

US3112192
Folder: Adverse Events
Form: Adverse Events (4)
Data signed: (b) (4) **19 Mar 2021 20:24:11**
Generated On: 09 Jun 2021 15:08:42

AEID	USA-US062-2020-MRNA-1273-P30 1000006
Adverse event	PAROXYSMAL ATRIAL FIBRILLATION
Was this a medically-attended AE?	Yes ■ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ■
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ■
Start date *(dd MMM yyyy)*	17 OCT 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ■
If not Ongoing, end date *(dd MMM yyyy)*	20 OCT 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ■
Is the adverse event serious?	Yes ■ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date *(dd MMM yyyy)*	17 OCT 2020
Hospital Discharge Date *(dd MMM yyyy)*	20 OCT 2020
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

	PATIENT REPORTS HAVING TAKEN BLOOD PRESSURE AT HOME AND HAVING HIGH READING IN EXCESS OF 195 SYSTOLIC. CALLED HOSPITAL AND WAS ADVISED TO PRESENT FOR ATRIAL FIBRILLATION. PATIENT ADMITTED ON 17OCT2020 AND DISCHARGED ON 20OCT2020. BLOOD WORK UNREMARKABLE, TROPONIN HS 5.9, HYPERCHLOREMIA 110. NO SIGNIFICANT CHANGE FOUND IN ECG. CXR REVIEWED AND NO ACTIVE DISEASE SHOWN. DIAGNOSIS OF PAROXYSMAL ATRIAL FIBRILLATION ASSESSED.
Serious Adverse Event Derived (CSA Programming Field Ony)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3112192
Folder: Adverse Events
Form: Adverse Events (5)
Data signed: (b) (4) **19 Mar 2021 20:24:11**
Generated On: 09 Jun 2021 15:08:42

AEID	
Adverse event	MUSCLE ACHE
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)*	11 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)*	01 OCT 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ■ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ■
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	

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

US3112192
Folder: Adverse Events
Form: Adverse Events (6)
Data signed: (b) (4) **19 Mar 2021 20:24:11**
Generated On: 09 Jun 2021 15:08:42

AEID	
Adverse event	GENERAL JOINT ACHES
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)*	11 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)*	01 OCT 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ■ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ■
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	

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

US3112192
Folder: Adverse Events
Form: Adverse Events (7)
Data signed: (b) (4) **19 Mar 2021 20:24:11**
Generated On: 09 Jun 2021 15:08:42

AEID	
Adverse event	FATIGUE
Was this a medically-attended AE?	Yes ☐ No ■
Was this a Solicited Adverse Reaction?	Yes ■ No ☐
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ■
Start date *(dd MMM yyyy)*	11 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)*	29 SEP 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ■ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ■
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	

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

US3112192
Folder: Adverse Events
Form: Adverse Events (8)
Data signed: (b) (4) **19 Mar 2021 20:24:11**
Generated On: 09 Jun 2021 15:08:42

AEID	
Adverse event	WORSENING SYMPTOMS OF ATRIAL FIBRILLATION
Was this a medically-attended AE?	Yes ■ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ■
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ■
Start date *(dd MMM yyyy)*	30 DEC 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ■
If not Ongoing, end date *(dd MMM yyyy)*	23 FEB 2021
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ■ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ■
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐

US3112192
Folder: Adverse Events
Form: Adverse Events (8)
Data signed: (b) (4) **19 Mar 2021 20:24:11**
Generated On: 09 Jun 2021 15:08:42

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

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Data signed: (b) (4) **02 Apr 2021 21:12:52**
Generated On: 09 Jun 2021 15:08:42

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

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

FDA-CBER-2022-1614-0507993

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

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	12 APR 2020
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Data signed: (b) (4) **15 Apr 2021 23:36:03**
Generated On: 09 Jun 2021 15:08:42

Name of Medication	LOSARTAN
Prophylaxis	Yes ☐ No ■
Indication	HYPERTENSION
Dose per administration	100
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

FDA-CBER-2022-1614-0507996

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	12 APR 2020
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

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

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2005
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

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

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

Name of Medication	NORCO
Prophylaxis	Yes ☐ No ■
Indication	LEFT KNEE CONTUSION SECONDARY TO MECHANICAL FALL
Dose per administration	10/325
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)*	2 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 ☐

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Data signed: (b) (4) **15 Apr 2021 23:36:03**
Generated On: 09 Jun 2021 15:08:42

Name of Medication	MORPHINE
Prophylaxis	Yes ☐ No ■
Indication	LEFT KNEE CONTUSION SECONDARY TO MECHANICAL FALL
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)*	2 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 ☐

Name of Medication	NORCO
Prophylaxis	Yes ☐ No ■
Indication	LEFT SHOULDER CONTUSION SECONDARY TO MECHANICAL FALL
Dose per administration	10/325
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ■ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐

	Intraocular ☐
	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	02 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	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 ☐

Name of Medication	MORPHINE
Prophylaxis	Yes ☐ No ■
Indication	LEFT SHOULDER CONTUSION SECONDARY TO MECHANICAL FALL
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)*	02 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 ☐

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Data signed: (b) (4) **15 Apr 2021 23:36:03**
Generated On: 09 Jun 2021 15:08:42

Name of Medication	AMLODIPINE
Prophylaxis	Yes ☐ No ■
Indication	HYPERTENSION
Dose per administration	54
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	12 APR 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	23 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 ■

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Data signed: (b) (4) **15 Apr 2021 23:36:03**
Generated On: 09 Jun 2021 15:08:42

Name of Medication	ATORVASTATIN
Prophylaxis	Yes ☐ No ■
Indication	HYPERCHOLESTEROLEMIA
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)*	25 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

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

	Intraocular ☐
	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	11 AUG 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	13 AUG 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 ☐

Name of Medication	MONTELUKAST
Prophylaxis	Yes ☐ No ■
Indication	ASTHMA
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)*	
Start date completely unknown	True
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 ☐

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

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Data signed: (b) (4) **15 Apr 2021 23:36:03**
Generated On: 09 Jun 2021 15:08:42

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

	Intramuscular ☐
	Respiratory (Inhalation) ■
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	18 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Data signed: (b) (4) **15 Apr 2021 23:36:03**
Generated On: 09 Jun 2021 15:08:42

Name of Medication	CLARITIN
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 ☐

	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	True
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 ☐

Name of Medication	FLUTICAZONE DISKUS
Prophylaxis	Yes ☐ No ■
Indication	SEASONAL ALLERGIES
Dose per administration	250
Dose unit	mg ☐ ug ■ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ■ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

	Intramuscular ☐ Respiratory (Inhalation) ■ Intralesional ☐ Intraperiteoneal ☐ Nasal ☐ Vaginal ☐ Rectal ☐ Intravenous ☐ Intravenous Bolus ☐ Intravenous Drip ☐ Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	21 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ■ No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Data signed: (b) (4) **15 Apr 2021 23:36:03**
Generated On: 09 Jun 2021 15:08:42

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

FDA-CBER-2022-1614-0508026

	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	True
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

Name of Medication	AMIODARONE
Prophylaxis	Yes ☐ No ■
Indication	ATRIAL FIBRILLATION
Dose per administration	200
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

FDA-CBER-2022-1614-0508028

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

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Data signed: (b) (4) **15 Apr 2021 23:36:03**
Generated On: 09 Jun 2021 15:08:42

Name of Medication	ASPIRIN
Prophylaxis	Yes ☐ No ■
Indication	PAROXYSMAL ATRIAL FIBRILLATION
Dose per administration	325
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ■ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐

	Intraocular ☐
	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	18 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	18 OCT 2020
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Data signed: (b) (4) **15 Apr 2021 23:36:03**
Generated On: 09 Jun 2021 15:08:42

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

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2019
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

US3112192
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Data signed: (b) (4) **02 Apr 2021 21:12:52**
Generated On: 09 Jun 2021 15:08:42

Were any concomitant procedures performed?	Yes ■ No ☐

If yes, please complete Concomitant Procedures form.

US3112192
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures
Data signed: (b) (4) **02 Apr 2021 21:12:52**
Generated On: 09 Jun 2021 15:08:42

Procedure/Surgery date *(dd MMM yyyy)*	Procedure/Surgery	Indication	If indication is Other, specify
23 FEB 2021	HEART ABLATION	Adverse Event	

FDA-CBER-2022-1614-0508035

US3112192
Folder: End of Study (1)
Form: Dosing Discontinuation
Generated On: 09 Jun 2021 15:08:42

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

US3112192
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 15:08:42

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

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Data signed: (b) (4) **02 Apr 2021 21:13:14**
Generated On: 09 Jun 2021 15:08:42

SAEID	USA-US062-2020-MRNA-1273-P301000006
Serious	Yes ■ No ☐
Death	Yes ☐ No ■
Life threatening	Yes ☐ No ■
Requires inpatient or prolongation of existing Hospitalization	Yes ■ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ■
Congenital anomaly or birth defect	Yes ☐ No ■
Other medically important event	Yes ☐ No ■
Investigator's First Name	LAURIE
Investigator's Last Name	HAN-CONRAD
Site Address: Street	9040 FRIARS RD ST 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form (1)
Data signed: (b) (4) **02 Apr 2021 21:13:14**
Generated On: 09 Jun 2021 15:08:42

SAEID	USA-US062-2020-MRNA-1273-P301000006
Serious	Yes ■ No ☐
Death	Yes ☐ No ■
Life threatening	Yes ☐ No ■
Requires inpatient or prolongation of existing Hospitalization	Yes ■ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ■
Congenital anomaly or birth defect	Yes ☐ No ■
Other medically important event	Yes ☐ No ■
Investigator's First Name	LAURIE
Investigator's Last Name	HAN-CONRAD
Site Address: Street	9040 FRIARS RD ST 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	23/OCT/2020 17:15
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

FDA-CBER-2022-1614-0508039

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form (2)
Data signed: (b) (4) **02 Apr 2021 21:13:14**
Generated On: 09 Jun 2021 15:08:42

SAEID	USA-US062-2020-MRNA-1273-P301000006
Serious	Yes ■ No ☐
Death	Yes ☐ No ■
Life threatening	Yes ☐ No ■
Requires inpatient or prolongation of existing Hospitalization	Yes ■ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ■
Congenital anomaly or birth defect	Yes ☐ No ■
Other medically important event	Yes ☐ No ■
Investigator's First Name	LAURIE
Investigator's Last Name	HAN-CONRAD
Site Address: Street	9040 FRIARS RD ST 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	03/NOV/2020 19:58
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form (3)
Data signed: (b) (4) **02 Apr 2021 21:13:14**
Generated On: 09 Jun 2021 15:08:42

SAEID	USA-US062-2020-MRNA-1273-P301000006
Serious	Yes ■ No ☐
Death	Yes ☐ No ■
Life threatening	Yes ☐ No ■
Requires inpatient or prolongation of existing Hospitalization	Yes ■ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ■
Congenital anomaly or birth defect	Yes ☐ No ■
Other medically important event	Yes ☐ No ■
Investigator's First Name	LAURIE
Investigator's Last Name	HAN-CONRAD
Site Address: Street	9040 FRIARS RD ST 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	06/NOV/2020 13:16
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form (4)
Data signed: (b) (4) **02 Apr 2021 21:13:14**
Generated On: 09 Jun 2021 15:08:42

SAEID	USA-US062-2020-MRNA-1273-P301000006
Serious	Yes ■ No ☐
Death	Yes ☐ No ■
Life threatening	Yes ☐ No ■
Requires inpatient or prolongation of existing Hospitalization	Yes ■ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ■
Congenital anomaly or birth defect	Yes ☐ No ■
Other medically important event	Yes ☐ No ■
Investigator's First Name	LAURIE
Investigator's Last Name	HAN-CONRAD
Site Address: Street	9040 FRIARS RD ST 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	18/NOV/2020 18:15
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form (5)
Data signed: (b) (4) **02 Apr 2021 21:13:14**
Generated On: 09 Jun 2021 15:08:42

SAEID	USA-US062-2020-MRNA-1273-P301000006
Serious	Yes ■ No ☐
Death	Yes ☐ No ■
Life threatening	Yes ☐ No ■
Requires inpatient or prolongation of existing Hospitalization	Yes ■ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ■
Congenital anomaly or birth defect	Yes ☐ No ■
Other medically important event	Yes ☐ No ■
Investigator's First Name	LAURIE
Investigator's Last Name	HAN-CONRAD
Site Address: Street	9040 FRIARS RD ST 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	19/NOV/2020 08:14
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

FDA-CBER-2022-1614-0508043

Audit

US3112192 (Prod: Medical Center For Clinical Research - M3 Wake Research)

US3112192
Form: Participant Creation
Generated On: 09 Jun 2021 15:08:42
Participant ID

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'US3112192'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Aug 2020 19:24:34

US3112192
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 15:08:42
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	11 Aug 2020 19:55:25

US3112192
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 15:08:42
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered '11 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Aug 2020 19:24:35

FDA-CBER-2022-1614-0508047

US3112192
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 15:08:42
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered 'Clinic (Clinic)'	Matthew Musikanth (b) (4)	11 Aug 2020 19:55:25

US3112192
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 15:08:42
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User entered 'SCRN'	System	11 Aug 2020 19:55:25

FDA-CBER-2022-1614-0508049

US3112192
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:08:42
Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered (b) (6) 1953'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Aug 2020 19:24:36

FDA-CBER-2022-1614-0508050

US3112192
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:08:42
Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered '67'	Matthew Musikanth (b) (4)	11 Aug 2020 23:53:26

US3112192
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:08:42
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User entered 'YEARS'	System	11 Aug 2020 23:53:26

US3112192
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:08:42
Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User entered '67'	System	11 Aug 2020 19:55:34

US3112192
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:08:42
Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered 'Female (F)'	Matthew Musikanth (b) (4)	11 Aug 2020 23:53:26

US3112192
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:08:42
Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Matthew Musikanth (b) (4)	11 Aug 2020 23:53:26

US3112192
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:08:42
White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:58:53
User entered '1'	Matthew Musikanth (b) (4)	11 Aug 2020 23:53:26

US3112192
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:08:42
Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered '0'	Matthew Musikanth (b) (4)	11 Aug 2020 23:53:26

US3112192
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:08:42
Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:58:53
User entered '0'	Matthew Musikanth (b) (4)	11 Aug 2020 23:53:26

US3112192
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:08:42
American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered '0'	Matthew Musikanth (b) (4)	11 Aug 2020 23:53:26

US3112192
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:08:42
Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered '0'	Matthew Musikanth (b) (4)	11 Aug 2020 23:53:26

US3112192
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:08:42
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered '0'	Matthew Musikanth (b) (4)	11 Aug 2020 23:53:26

US3112192
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:08:42
If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered empty.	Matthew Musikanth (b) (4)	11 Aug 2020 23:53:26

US3112192
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:08:42
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered '0'	Matthew Musikanth (b) (4)	11 Aug 2020 23:53:26

US3112192
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 15:08:42
Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:58:53
User entered '0'	Matthew Musikanth (b) (4)	11 Aug 2020 23:53:26

US3112192
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 15:08:42
Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered '11 Aug 2020'	Matthew Musikanth (b) (4)	11 Aug 2020 19:55:34

FDA-CBER-2022-1614-0508065

US3112192
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 15:08:42
Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User entered 'Aug 2020'	System	11 Aug 2020 19:55:34

US3112192
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 15:08:42
Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User entered '2020'	System	11 Aug 2020 19:55:34

FDA-CBER-2022-1614-0508067

US3112192
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 15:08:42
Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered 'Amendment 2 (2)'	Matthew Musikanth (b) (4)	11 Aug 2020 19:55:34

FDA-CBER-2022-1614-0508068

US3112192
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 15:08:42
Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	11 Aug 2020 19:55:34

US3112192
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 15:08:42
If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered empty.	Matthew Musikanth (b) (4)	11 Aug 2020 19:55:34

US3112192
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 15:08:42
If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered empty.	Matthew Musikanth (b) (4)	11 Aug 2020 19:55:34

US3112192
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 15:08:42
Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered 'No (N)'	Matthew Musikanth (b) (4)	11 Aug 2020 19:55:34

US3112192
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 15:08:42
If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Aug 2020 19:24:35

US3112192
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 15:08:42
Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User entered '1'	System	11 Aug 2020 19:55:39

US3112192
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Generated On: 09 Jun 2021 15:08:42
Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	11 Aug 2020 19:55:39

US3112192
Folder: Screening
Form: Medical History Summary
Generated On: 09 Jun 2021 15:08:42
Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:58:53
User closed query 'Per CDM: Age of the subject is >25 years. however, no medical history is collected. Please confirm or update as needed, else please clarify.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 03:51:42
Query 'Per CDM: Age of the subject is >25 years. however, no medical history is collected. Please confirm or update as needed, else please clarify.' answered with 'Updated.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 22:36:37
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 22:36:30
User opened query 'Per CDM: Age of the subject is >25 years. however, no medical history is collected. Please confirm or update as needed, else please clarify.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 11:03:32
User entered 'No (N)'	Matthew Musikanth (b) (4)	11 Aug 2020 23:56:11

US3112192
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 15:08:42
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal stenosis and obstruction, HLT: Gastrointestinal stenosis and obstruction NEC, PT: Intestinal obstruction, LLT: Bowel obstruction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 22:38:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 22:38:56
Data point term sent to Coder	System	08 Sep 2020 22:37:46
User entered 'Bowel Blockage'	(b) (4), (b) (6)	08 Sep 2020 22:37:03

US3112192
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 15:08:42
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:58:53
User entered 'UN Apr 2020'	(b) (4), (b) (6)	08 Sep 2020 22:37:03

FDA-CBER-2022-1614-0508078

US3112192
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 15:08:42
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:58:53
User entered '0'	(b) (4), (b) (6)	08 Sep 2020 22:37:03

US3112192
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 15:08:42
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:58:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 22:37:03

US3112192
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 15:08:42
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:58:53
User entered empty.	(b) (4), (b) (6) (b) (4)	08 Sep 2020 22:37:03

US3112192
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 15:08:42
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:58:53
User entered '0'	(b) (4), (b) (6) (b) (4)	08 Sep 2020 22:37:03

US3112192
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 15:08:42
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User entered 'Apr 2020'	System	08 Sep 2020 22:37:03

US3112192
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 15:08:42
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User entered '2020'	System	08 Sep 2020 22:37:03

FDA-CBER-2022-1614-0508084

US3112192
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 15:08:42
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User entered empty.	System	08 Sep 2020 22:37:03

FDA-CBER-2022-1614-0508085

US3112192
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 15:08:42
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User entered empty.	System	08 Sep 2020 22:37:03

FDA-CBER-2022-1614-0508086

US3112192
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 15:08:42
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 22:38:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 22:38:57
Data point term sent to Coder	System	08 Sep 2020 22:37:44
User entered 'Hypertension'	(b) (4), (b) (6)	08 Sep 2020 22:37:27

US3112192
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 15:08:42
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:58:53
User entered 'UN Apr 2020'	(b) (4), (b) (6)	08 Sep 2020 22:37:27

US3112192
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 15:08:42
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:58:53
User entered '0'	(b) (4), (b) (6) (b) (4)	08 Sep 2020 22:37:27

US3112192
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 15:08:42
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:58:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Sep 2020 22:37:27

US3112192
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 15:08:42
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:58:53
User entered empty.	(b) (4), (b) (6) (b) (4)	08 Sep 2020 22:37:27

US3112192
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 15:08:42
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:58:53
User entered '0'	(b) (4), (b) (6) (b) (4)	08 Sep 2020 22:37:27

US3112192
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 15:08:42
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User entered 'Apr 2020'	System	08 Sep 2020 22:37:27

FDA-CBER-2022-1614-0508093

US3112192
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 15:08:42
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User entered '2020'	System	08 Sep 2020 22:37:27

FDA-CBER-2022-1614-0508094

US3112192
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 15:08:42
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User entered empty.	System	08 Sep 2020 22:37:27

US3112192
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 15:08:42
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User entered empty.	System	08 Sep 2020 22:37:27

FDA-CBER-2022-1614-0508096

US3112192
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 15:08:42
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:58:53
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 15:35:21
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'Gallstones 2013 -2013' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 15:02:37
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 12:16:15
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)	08 Sep 2020 22:40:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 22:40:59
Data point term sent to Coder	System	08 Sep 2020 22:39:52
User entered 'Cholecystectomy'	(b) (4), (b) (6)	08 Sep 2020 22:38:54

US3112192
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 15:08:42
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:58:53
User entered 'UN UNK 2013'	(b) (4), (b) (6)	08 Sep 2020 22:38:54

FDA-CBER-2022-1614-0508098

US3112192
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 15:08:42
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:58:53
User entered '0'	(b) (4), (b) (6) (b) (4)	08 Sep 2020 22:38:54

US3112192
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 15:08:42
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:58:53
User entered 'No (N)'	(b) (4), (b) (6) (b) (4)	08 Sep 2020 22:38:54

US3112192
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 15:08:42
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:58:53
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	08 Sep 2020 22:39:01
User entered 'UN UNK 2013' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Sep 2020 22:39:01
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	08 Sep 2020 22:38:54
User entered ' 2013' (non-conformant).	(b) (4), (b) (6)	08 Sep 2020 22:38:54

US3112192
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 15:08:42
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:58:53
User entered '0'	(b) (4), (b) (6) (b) (4)	08 Sep 2020 22:38:54

US3112192
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 15:08:42
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User entered 'Jan 2013'	System	08 Sep 2020 22:38:54

US3112192
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 15:08:42
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User entered '2013'	System	08 Sep 2020 22:38:54

FDA-CBER-2022-1614-0508104

US3112192
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 15:08:42
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User entered 'Jan 2013'	System	08 Sep 2020 22:39:01
User entered empty.	System	08 Sep 2020 22:38:54

US3112192
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 15:08:42
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User entered '2013'	System	08 Sep 2020 22:39:01
User entered empty.	System	08 Sep 2020 22:38:54

US3112192
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 15:08:42
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 18:05:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 18:05:59
Data point term sent to Coder	System	30 Sep 2020 18:04:24
User entered 'atrial fibrillation'	Karen Mylerberg (b) (4) (b) (4)	30 Sep 2020 18:03:41

FDA-CBER-2022-1614-0508107

US3112192
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 15:08:42
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered 'UN Apr 2020'	Karen Mylerberg (b) (4) (b) (4)	30 Sep 2020 18:03:41

US3112192
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 15:08:42
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered '0'	Karen Mylerberg (b) (4) (b) (4)	30 Sep 2020 18:03:41

US3112192
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 15:08:42
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	30 Sep 2020 18:03:41

US3112192
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 15:08:42
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	30 Sep 2020 18:03:41

US3112192
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 15:08:42
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered '0'	Karen Mylerberg (b) (4) (b) (4)	30 Sep 2020 18:03:41

US3112192
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 15:08:42
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User entered 'Apr 2020'	System	30 Sep 2020 18:03:41

US3112192
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 15:08:42
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User entered '2020'	System	30 Sep 2020 18:03:41

FDA-CBER-2022-1614-0508114

US3112192
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 15:08:42
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User entered empty.	System	30 Sep 2020 18:03:41

US3112192
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 15:08:42
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User entered empty.	System	30 Sep 2020 18:03:41

US3112192
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 15:08:42
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 18:09:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 18:09:58
Data point term sent to Coder	System	30 Sep 2020 18:08:39
User entered 'hypercholesterolemia'	Karen Mylerberg (b) (4) (b) (4)	30 Sep 2020 18:08:05

US3112192
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 15:08:42
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered 'UN UNK 2018'	Karen Mylerberg (b) (4) (b) (4)	30 Sep 2020 18:08:05

US3112192
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 15:08:42
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered '0'	Karen Mylerberg (b) (4) (b) (4)	30 Sep 2020 18:08:05

US3112192
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 15:08:42
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	30 Sep 2020 18:08:05

US3112192
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 15:08:42
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	30 Sep 2020 18:08:05

US3112192
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 15:08:42
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered '0'	Karen Mylerberg (b) (4) (b) (4)	30 Sep 2020 18:08:05

US3112192
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 15:08:42
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User entered 'Jan 2018'	System	30 Sep 2020 18:08:05

US3112192
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 15:08:42
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User entered '2018'	System	30 Sep 2020 18:08:05

FDA-CBER-2022-1614-0508124

US3112192
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 15:08:42
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User entered empty.	System	30 Sep 2020 18:08:05

US3112192
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 15:08:42
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User entered empty.	System	30 Sep 2020 18:08:05

US3112192
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 15:08:42
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholelithiasis, LLT: Gallstones - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 15:16:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 15:16:26
Data point term sent to Coder	System	13 Oct 2020 15:15:14
User entered 'Gall stones'	(b) (4), (b) (6)	13 Oct 2020 15:14:46

US3112192
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 15:08:42
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:58:53
User entered 'UN UNK 2013'	(b) (4), (b) (6) (b) (4)	13 Oct 2020 15:14:46

FDA-CBER-2022-1614-0508128

US3112192
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 15:08:42
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:58:53
User entered '0'	(b) (4), (b) (6) (b) (4)	13 Oct 2020 15:14:46

US3112192
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 15:08:42
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:58:53
User entered 'No (N)'	(b) (4), (b) (6) (b) (4)	13 Oct 2020 15:14:46

FDA-CBER-2022-1614-0508130

US3112192
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 15:08:42
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:58:53
User entered 'UN UNK 2013'	(b) (4), (b) (6)	13 Oct 2020 15:14:46

US3112192
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 15:08:42
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:58:53
User entered '0'	(b) (4), (b) (6) (b) (4)	13 Oct 2020 15:14:46

US3112192
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 15:08:42
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User entered 'Jan 2013'	System	13 Oct 2020 15:14:46

US3112192
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 15:08:42
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User entered '2013'	System	13 Oct 2020 15:14:46

FDA-CBER-2022-1614-0508134

US3112192
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 15:08:42
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User entered 'Jan 2013'	System	13 Oct 2020 15:14:46

US3112192
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 15:08:42
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User entered '2013'	System	13 Oct 2020 15:14:46

FDA-CBER-2022-1614-0508136

US3112192
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 15:08:42
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:58:53
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Neck pain, LLT: Neck pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 15:53:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 15:53:19
Data point term sent to Coder	System	02 Nov 2020 21:59:36
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Nov 2020 21:59:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Nov 2020 21:59:31
User entered 'Chronic Neck Pain' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	02 Nov 2020 21:59:31
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Nov 2020 21:57:59
User entered empty.	Matthew Musikanth (b) (4)	02 Nov 2020 21:57:59
DataPoint activated with code reason code Data required.	Matthew Musikanth (b) (4)	02 Nov 2020 21:57:30
DataPoint inactivated with code reason code Data not required.	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 16:58:08

US3112192
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 15:08:42
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:58:53
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	02 Nov 2020 21:59:31
User entered 'un UNK 2012' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	02 Nov 2020 21:59:31
User opened query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	02 Nov 2020 21:57:59
User entered empty.	Matthew Musikanth (b) (4)	02 Nov 2020 21:57:59
DataPoint activated with code reason code Data required.	Matthew Musikanth (b) (4)	02 Nov 2020 21:57:30
DataPoint inactivated with code reason code Data not required.	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 16:58:08

US3112192
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 15:08:42
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:58:53
User entered '0'	Matthew Musikanth (b) (4)	02 Nov 2020 21:57:59
DataPoint activated with code reason code Data required.	Matthew Musikanth (b) (4)	02 Nov 2020 21:57:30
DataPoint inactivated with code reason code Data not required.	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 16:58:08

US3112192
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 15:08:42
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Nov 2020 21:59:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Nov 2020 21:59:31
User entered 'Yes (Y)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	02 Nov 2020 21:59:31
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Nov 2020 21:57:59
User entered empty.	Matthew Musikanth (b) (4)	02 Nov 2020 21:57:59
DataPoint activated with code reason code Data required.	Matthew Musikanth (b) (4)	02 Nov 2020 21:57:30
DataPoint inactivated with code reason code Data not required.	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 16:58:08

US3112192
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 15:08:42
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:58:53
User entered empty.	Matthew Musikanth (b) (4)	02 Nov 2020 21:57:59
DataPoint activated with code reason code Data required.	Matthew Musikanth (b) (4)	02 Nov 2020 21:57:30
DataPoint inactivated with code reason code Data not required.	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 16:58:08

US3112192
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 15:08:42
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered '0'	Matthew Musikanth (b) (4)	02 Nov 2020 21:57:59
DataPoint activated with code reason code Data required.	Matthew Musikanth (b) (4)	02 Nov 2020 21:57:30
DataPoint inactivated with code reason code Data not required.	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 16:58:08

US3112192
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 15:08:42
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User entered 'Jan 2012'	System	02 Nov 2020 21:59:31
User entered empty.	System	02 Nov 2020 21:57:59
DataPoint activated with code reason code Data required.	Matthew Musikanth (b) (4)	02 Nov 2020 21:57:30
DataPoint inactivated with code reason code Data not required.	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 16:58:08

US3112192
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 15:08:42
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User entered '2012'	System	02 Nov 2020 21:59:31
User entered empty.	System	02 Nov 2020 21:57:59
DataPoint activated with code reason code Data required.	Matthew Musikanth (b) (4)	02 Nov 2020 21:57:30
DataPoint inactivated with code reason code Data not required.	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 16:58:08

US3112192
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 15:08:42
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User entered empty.	System	02 Nov 2020 21:57:59
DataPoint activated with code reason code Data required.	Matthew Musikanth (b) (4)	02 Nov 2020 21:57:30
DataPoint inactivated with code reason code Data not required.	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 16:58:08

US3112192
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 15:08:42
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User entered empty.	System	02 Nov 2020 21:57:59
DataPoint activated with code reason code Data required.	Matthew Musikanth (b) (4)	02 Nov 2020 21:57:30
DataPoint inactivated with code reason code Data not required.	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 16:58:08

US3112192
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 15:08:42
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
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)	05 Nov 2020 19:13:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 19:13:21
Data point term sent to Coder	System	05 Nov 2020 19:13:14
User entered 'Depression'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:12:56

US3112192
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 15:08:42
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered 'un UNK 2016'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:12:56

FDA-CBER-2022-1614-0508148

US3112192
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 15:08:42
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered '0'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:12:56

US3112192
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 15:08:42
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:12:56

US3112192
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 15:08:42
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered empty.	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:12:56

FDA-CBER-2022-1614-0508151

US3112192
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 15:08:42
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered '0'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:12:56

US3112192
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 15:08:42
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User entered 'Jan 2016'	System	05 Nov 2020 19:12:56

US3112192
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 15:08:42
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User entered '2016'	System	05 Nov 2020 19:12:56

FDA-CBER-2022-1614-0508154

US3112192
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 15:08:42
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User entered empty.	System	05 Nov 2020 19:12:56

US3112192
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 15:08:42
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User entered empty.	System	05 Nov 2020 19:12:56

FDA-CBER-2022-1614-0508156

US3112192
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 15:08:42
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 21:33:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 21:33:40
Data point term sent to Coder	System	10 Nov 2020 21:33:05
User entered 'asthma'	Natalie Moy (b) (4) (b) (4)	10 Nov 2020 21:32:11

US3112192
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 15:08:42
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered empty.	Natalie Moy (b) (4) (b) (4)	10 Nov 2020 21:32:11

FDA-CBER-2022-1614-0508158

US3112192
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 15:08:42
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered '1'	Natalie Moy (b) (4) (b) (4)	10 Nov 2020 21:32:11

US3112192
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 15:08:42
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	10 Nov 2020 21:32:11

US3112192
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 15:08:42
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered empty.	Natalie Moy (b) (4) (b) (4)	10 Nov 2020 21:32:11

FDA-CBER-2022-1614-0508161

US3112192
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 15:08:42
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered '0'	Natalie Moy (b) (4) (b) (4)	10 Nov 2020 21:32:11

US3112192
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 15:08:42
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User entered empty.	System	10 Nov 2020 21:32:11

FDA-CBER-2022-1614-0508163

US3112192
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 15:08:42
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User entered empty.	System	10 Nov 2020 21:32:11

FDA-CBER-2022-1614-0508164

US3112192
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 15:08:42
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User entered empty.	System	10 Nov 2020 21:32:11

FDA-CBER-2022-1614-0508165

US3112192
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 15:08:42
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User entered empty.	System	10 Nov 2020 21:32:11

FDA-CBER-2022-1614-0508166

US3112192
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 15:08:42
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User coded data point as SOC: Gastrointestinal disorders, HLGT: Benign neoplasms gastrointestinal, HLT: Benign neoplasms gastrointestinal (excl oral cavity), PT: Large intestine polyp, LLT: Colonic polyp - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 21:33:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 21:33:39
Data point term sent to Coder	System	10 Nov 2020 21:33:06
User entered 'colon polyps'	Natalie Moy (b) (4) (b) (4)	10 Nov 2020 21:32:27

US3112192
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 15:08:42
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered 'un UNK 2017'	Natalie Moy (b) (4) (b) (4)	10 Nov 2020 21:32:27

US3112192
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 15:08:42
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered '0'	Natalie Moy (b) (4) (b) (4)	10 Nov 2020 21:32:27

US3112192
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 15:08:42
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	10 Nov 2020 21:32:27

US3112192
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 15:08:42
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered empty.	Natalie Moy (b) (4) (b) (4)	10 Nov 2020 21:32:27

FDA-CBER-2022-1614-0508171

US3112192
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 15:08:42
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered '0'	Natalie Moy (b) (4) (b) (4)	10 Nov 2020 21:32:27

US3112192
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 15:08:42
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User entered 'Jan 2017'	System	10 Nov 2020 21:32:27

FDA-CBER-2022-1614-0508173

US3112192
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 15:08:42
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User entered '2017'	System	10 Nov 2020 21:32:27

FDA-CBER-2022-1614-0508174

US3112192
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 15:08:42
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User entered empty.	System	10 Nov 2020 21:32:27

FDA-CBER-2022-1614-0508175

US3112192
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 15:08:42
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User entered empty.	System	10 Nov 2020 21:32:27

FDA-CBER-2022-1614-0508176

US3112192
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 15:08:42
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
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)	17 Nov 2020 21:24:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 21:24:50
Data point term sent to Coder	System	17 Nov 2020 21:23:30
User entered 'seasonal allergies'	Natalie Moy (b) (4) (b) (4)	17 Nov 2020 21:22:32

US3112192
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 15:08:42
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered 'un UNK 2000'	Natalie Moy (b) (4) (b) (4)	17 Nov 2020 21:22:32

US3112192
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 15:08:42
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered '0'	Natalie Moy (b) (4) (b) (4)	17 Nov 2020 21:22:32

US3112192
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 15:08:42
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	17 Nov 2020 21:22:32

FDA-CBER-2022-1614-0508180

US3112192
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 15:08:42
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered empty.	Natalie Moy (b) (4) (b) (4)	17 Nov 2020 21:22:32

US3112192
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 15:08:42
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered '0'	Natalie Moy (b) (4) (b) (4)	17 Nov 2020 21:22:32

US3112192
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 15:08:42
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User entered 'Jan 2000'	System	17 Nov 2020 21:22:32

US3112192
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 15:08:42
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User entered '2000'	System	17 Nov 2020 21:22:32

US3112192
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 15:08:42
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User entered empty.	System	17 Nov 2020 21:22:32

FDA-CBER-2022-1614-0508185

US3112192
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 15:08:42
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User entered empty.	System	17 Nov 2020 21:22:32

FDA-CBER-2022-1614-0508186

US3112192
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	12 Aug 2020 00:00:05

US3112192
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered '11 Aug 2020'	Matthew Musikanth (b) (4)	12 Aug 2020 00:00:05

FDA-CBER-2022-1614-0508188

US3112192
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered '12:07'	Matthew Musikanth (b) (4)	12 Aug 2020 00:00:05

US3112192
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User entered '11 Aug 2020 12:07'	System	12 Aug 2020 00:00:05

US3112192
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:58:53
User entered '63' in	Matthew Musikanth (b) (4)	12 Aug 2020 00:00:05
DataPoint set to visible.	System	11 Aug 2020 19:55:39

FDA-CBER-2022-1614-0508191

US3112192
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:58:53
User entered '171.8' lb	(b) (4) Matthew Musikanth	12 Aug 2020 00:00:05
DataPoint set to visible.	(b) (4) System	11 Aug 2020 19:55:39

US3112192
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
Amendment Manager: User entered '30.49664'	System	16 Sep 2020 23:52:21
User entered '30.5'	System	12 Aug 2020 00:00:05
DataPoint set to visible.	System	11 Aug 2020 19:55:39

US3112192
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User entered 'kg/m2'	System	12 Aug 2020 00:00:05
DataPoint set to visible.	System	11 Aug 2020 19:55:39

US3112192
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:58:53
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 03:46:11
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' answered with 'Updated' (Site from DM).	Karen Mylerberg (b) (4)	05 Sep 2020 14:56:27
User entered missing code ND - Not Done; reason for change Data Entry Error	Karen Mylerberg (b) (4)	05 Sep 2020 14:56:20
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	21 Aug 2020 15:08:21
User entered '98.9' F	Matthew Musikanth (b) (4)	12 Aug 2020 00:00:05

FDA-CBER-2022-1614-0508195

US3112192
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered empty; reason for change Data Entry Error	Karen Mylerberg (b) (4) (b) (4)	05 Sep 2020 14:56:20
User entered 'Oral (Oral)'	Matthew Musikanth (b) (4)	12 Aug 2020 00:00:05

US3112192
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered empty.	Matthew Musikanth (b) (4)	12 Aug 2020 00:00:05

US3112192
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered missing code ND - Not Done; reason for change Data Entry Error	Karen Mylerberg (b) (4) (b) (4)	05 Sep 2020 14:56:20
User entered '62'	Matthew Musikanth (b) (4)	12 Aug 2020 00:00:05

US3112192
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User entered 'bpm'	System	12 Aug 2020 00:00:05

US3112192
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered missing code ND - Not Done; reason for change Data Entry Error	Karen Mylerberg (b) (4) (b) (4)	05 Sep 2020 14:56:20
User entered '16'	Matthew Musikanth (b) (4)	12 Aug 2020 00:00:05

US3112192
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User entered 'breaths/min'	System	12 Aug 2020 00:00:05

FDA-CBER-2022-1614-0508201

US3112192
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered missing code ND - Not Done; reason for change Data Entry Error	Karen Mylerberg (b) (4) (b) (4)	05 Sep 2020 14:56:20
User entered '135'	Matthew Musikanth (b) (4)	12 Aug 2020 00:00:05

US3112192
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User entered 'mmHg'	System	12 Aug 2020 00:00:05

FDA-CBER-2022-1614-0508203

US3112192
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered missing code ND - Not Done; reason for change Data Entry Error	Karen Mylerberg (b) (4) (b) (4)	05 Sep 2020 14:56:20
User entered '76'	Matthew Musikanth (b) (4)	12 Aug 2020 00:00:05

US3112192
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User entered 'mmHg'	System	12 Aug 2020 00:00:05

FDA-CBER-2022-1614-0508205

US3112192
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37

FDA-CBER-2022-1614-0508206

US3112192
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37

FDA-CBER-2022-1614-0508207

US3112192
Folder: Screening
Form: Physical Examination
Generated On: 09 Jun 2021 15:08:42
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	12 Aug 2020 00:00:21

US3112192
Folder: Screening
Form: Physical Examination
Generated On: 09 Jun 2021 15:08:42
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:58:53
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	13 Sep 2020 03:00:21
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	11 Sep 2020 18:02:56
User entered '11 Aug 2020'	Matthew Musikanth (b) (4)	12 Aug 2020 00:00:21

US3112192
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 15:08:42
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered '11 Aug 2020'	Matthew Musikanth (b) (4)	12 Aug 2020 00:01:02

US3112192
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 15:08:42
Is the participant of childbearing potential?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered 'No (N)'	Matthew Musikanth (b) (4)	12 Aug 2020 00:01:02

US3112192
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 15:08:42
If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered 'Surgically sterile (SURGICALLY STERILE)'	Matthew Musikanth (b) (4)	12 Aug 2020 00:01:02

US3112192
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 15:08:42
If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered empty.	Matthew Musikanth (b) (4)	12 Aug 2020 00:01:02

US3112192
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 15:08:42
If Surgically sterile, date of surgery *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered 'un UNK 1978'	Matthew Musikanth (b) (4)	12 Aug 2020 00:01:02

US3112192
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 15:08:42
Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered '0'	Matthew Musikanth (b) (4)	12 Aug 2020 00:01:02

US3112192
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 15:08:42
If Post-menopausal, date of last menstruation *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered empty.	Matthew Musikanth (b) (4)	12 Aug 2020 00:01:02

US3112192
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 15:08:42
Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered '0'	Matthew Musikanth (b) (4)	12 Aug 2020 00:01:02

US3112192
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:08:42
Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered 'No (N)'	Matthew Musikanth (b) (4)	12 Aug 2020 00:01:25

US3112192
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:08:42
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered 'No (N)'	Matthew Musikanth (b) (4)	12 Aug 2020 00:01:25

US3112192
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:08:42
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)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered 'No (N)'	Matthew Musikanth (b) (4)	12 Aug 2020 00:01:25

US3112192
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:08:42
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)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered 'No (N)'	Matthew Musikanth (b) (4)	12 Aug 2020 00:01:25

US3112192
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:08:42
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered 'No (N)'	Matthew Musikanth (b) (4)	12 Aug 2020 00:01:25

US3112192
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:08:42
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)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered 'No (N)'	Matthew Musikanth (b) (4)	12 Aug 2020 00:01:25

US3112192
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:08:42
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)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered 'No (N)'	Matthew Musikanth (b) (4)	12 Aug 2020 00:01:25

US3112192
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:08:42
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)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered 'No (N)'	Matthew Musikanth (b) (4)	12 Aug 2020 00:01:25

US3112192
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:08:42
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)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered 'No (N)'	Matthew Musikanth (b) (4)	12 Aug 2020 00:01:25

US3112192
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:08:42
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)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered 'No (N)'	Matthew Musikanth (b) (4)	12 Aug 2020 00:01:25

US3112192
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:08:42
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)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered 'No (N)'	Matthew Musikanth (b) (4)	12 Aug 2020 00:01:25

US3112192
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:08:42
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered 'No (N)'	Matthew Musikanth (b) (4)	12 Aug 2020 00:01:25

US3112192
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:08:42
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered empty.	Matthew Musikanth (b) (4)	12 Aug 2020 00:01:25

US3112192
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:08:42
No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered '0'	Matthew Musikanth (b) (4)	12 Aug 2020 00:01:25

US3112192
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:08:42
Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered '0'	Matthew Musikanth (b) (4)	12 Aug 2020 00:01:25

US3112192
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:08:42
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)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered '0'	Matthew Musikanth (b) (4)	12 Aug 2020 00:01:25

US3112192
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:08:42
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)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered '0'	Matthew Musikanth (b) (4)	12 Aug 2020 00:01:25

US3112192
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:08:42
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)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered '0'	Matthew Musikanth (b) (4)	12 Aug 2020 00:01:25

US3112192
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:08:42
Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered '1'	Matthew Musikanth (b) (4)	12 Aug 2020 00:01:25

US3112192
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:08:42
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered '0'	Matthew Musikanth (b) (4)	12 Aug 2020 00:01:25

US3112192
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 15:08:42
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:32:37
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	19 Feb 2021 16:58:53
User entered empty.	Matthew Musikanth (b) (4)	12 Aug 2020 00:01:25

US3112192
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 15:08:42
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:01:30
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	12 Aug 2020 00:01:37

US3112192
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 15:08:42
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:01:30
User entered '11 Aug 2020'	Matthew Musikanth (b) (4)	12 Aug 2020 00:01:37

FDA-CBER-2022-1614-0508240

US3112192
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 15:08:42
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:01:30
User entered 'Clinic (Clinic)'	Matthew Musikanth (b) (4)	12 Aug 2020 00:01:37

US3112192
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 15:08:42
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User entered 'VISIT1'	System	12 Aug 2020 00:01:37

FDA-CBER-2022-1614-0508242

US3112192
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 15:08:42
What was the date of randomization? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered '11 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Aug 2020 19:24:37

FDA-CBER-2022-1614-0508243

US3112192
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 15:08:42
What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 03:40:57
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:40:57
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Aug 2020 19:24:37
User entered '185678' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Aug 2020 19:24:37

FDA-CBER-2022-1614-0508244

US3112192
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 15:08:42
In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	11 Aug 2020 19:24:37

FDA-CBER-2022-1614-0508245

US3112192
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 15:08:42
Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:01:30
User entered 'No (N)'	Matthew Musikanth (b) (4)	12 Aug 2020 00:01:53

US3112192
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 15:08:42

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:01:30
User entered 'No (N)'	Matthew Musikanth (b) (4)	12 Aug 2020 00:01:53

US3112192
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 15:08:42
Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:01:30
User entered 'No (N)'	Matthew Musikanth (b) (4)	12 Aug 2020 00:01:53

US3112192
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 15:08:42
Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:01:30
User entered 'No (N)'	Matthew Musikanth (b) (4)	12 Aug 2020 00:01:53

US3112192
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 15:08:42
Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:01:30
User entered 'No (N)'	Matthew Musikanth (b) (4)	12 Aug 2020 00:01:53

US3112192
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 15:08:42
Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:01:30
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	25 Sep 2020 20:03:52
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:17:57
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:36:14

US3112192
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:08:42
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:01:30
User entered missing code ND - Not Done.	Matthew Musikanth (b) (4)	12 Aug 2020 00:05:09

US3112192
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:08:42
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered missing code ND - Not Done.	Matthew Musikanth (b) (4)	12 Aug 2020 00:05:09

US3112192
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:08:42
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:01:30
User entered missing code ND - Not Done.	Matthew Musikanth (b) (4)	12 Aug 2020 00:05:09

US3112192
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:08:42
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:01:30
User entered missing code ND - Not Done.	Matthew Musikanth (b) (4)	12 Aug 2020 00:05:09

US3112192
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:08:42
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User accepted default value 'Pre-Dose (PREDOSE)'	Matthew Musikanth (b) (4)	12 Aug 2020 00:05:09

US3112192
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:08:42
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	12 Aug 2020 00:05:09

US3112192
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:08:42
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:01:30
User entered '11 Aug 2020'	Matthew Musikanth (b) (4)	12 Aug 2020 00:05:09

FDA-CBER-2022-1614-0508258

US3112192
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:08:42
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:01:30
User entered '12:07'	Matthew Musikanth (b) (4)	12 Aug 2020 00:05:09

FDA-CBER-2022-1614-0508259

US3112192
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:08:42
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User entered '11 Aug 2020 12:07'	System	12 Aug 2020 00:05:09

US3112192
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:08:42
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:01:30
User entered '98.9' F	Matthew Musikanth (b) (4)	12 Aug 2020 00:05:09

US3112192
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:08:42
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:01:30
User entered 'Oral (Oral)'	Matthew Musikanth (b) (4)	12 Aug 2020 00:05:09

US3112192
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:08:42
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:01:30
User entered empty.	Matthew Musikanth (b) (4)	12 Aug 2020 00:05:09

FDA-CBER-2022-1614-0508263

US3112192
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:08:42
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:01:30
User entered '62'	Matthew Musikanth (b) (4)	12 Aug 2020 00:05:09

US3112192
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:08:42
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User entered 'bpm'	System	12 Aug 2020 00:05:09

FDA-CBER-2022-1614-0508265

US3112192
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:08:42
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered '16'	Matthew Musikanth (b) (4)	12 Aug 2020 00:05:09

US3112192
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:08:42
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User entered 'breaths/min'	System	12 Aug 2020 00:05:09

FDA-CBER-2022-1614-0508267

US3112192
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:08:42
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:01:30
User entered '135'	Matthew Musikanth (b) (4)	12 Aug 2020 00:05:09

US3112192
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:08:42
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User entered 'mmHg'	System	12 Aug 2020 00:05:09

FDA-CBER-2022-1614-0508269

US3112192
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:08:42
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:01:30
User entered '76'	Matthew Musikanth (b) (4)	12 Aug 2020 00:05:09

FDA-CBER-2022-1614-0508270

US3112192
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:08:42
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User entered 'mmHg'	System	12 Aug 2020 00:05:09

FDA-CBER-2022-1614-0508271

US3112192
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:08:42
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:01:30
User entered missing code ND - Not Done.	Matthew Musikanth (b) (4)	12 Aug 2020 00:05:09

US3112192
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:08:42
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:01:30
User entered missing code ND - Not Done.	Matthew Musikanth (b) (4)	12 Aug 2020 00:05:09

FDA-CBER-2022-1614-0508273

US3112192
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:08:42
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User accepted default value 'Post-Dose (POSTDOSE)'	Matthew Musikanth (b) (4)	12 Aug 2020 00:05:09

FDA-CBER-2022-1614-0508274

US3112192
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:08:42
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	12 Aug 2020 00:05:09

FDA-CBER-2022-1614-0508275

US3112192
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:08:42
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:01:30
User entered '11 Aug 2020'	Matthew Musikanth (b) (4)	12 Aug 2020 00:05:09

US3112192
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:08:42
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:01:30
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	17 Aug 2020 16:29:12
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	System	12 Aug 2020 00:05:09
User entered '13:20'	Matthew Musikanth (b) (4)	12 Aug 2020 00:05:09

US3112192
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:08:42
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User entered '11 Aug 2020 13:20'	System	12 Aug 2020 00:05:09

FDA-CBER-2022-1614-0508278

US3112192
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:08:42
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:01:30
User entered '99.1' F	Matthew Musikanth (b) (4)	12 Aug 2020 00:05:09

US3112192
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:08:42
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered 'Oral (Oral)'	Matthew Musikanth (b) (4)	12 Aug 2020 00:05:09

US3112192
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:08:42
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered empty.	Matthew Musikanth (b) (4)	12 Aug 2020 00:05:09

US3112192
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:08:42
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:01:30
User entered '66'	Matthew Musikanth (b) (4)	12 Aug 2020 00:05:09

FDA-CBER-2022-1614-0508282

US3112192
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:08:42
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User entered 'bpm'	System	12 Aug 2020 00:05:09

FDA-CBER-2022-1614-0508283

US3112192
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:08:42
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered '18'	Matthew Musikanth (b) (4)	12 Aug 2020 00:05:09

US3112192
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:08:42
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User entered 'breaths/min'	System	12 Aug 2020 00:05:09

US3112192
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:08:42
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:01:30
User entered '126'	Matthew Musikanth (b) (4)	12 Aug 2020 00:05:09

FDA-CBER-2022-1614-0508286

US3112192
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:08:42
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User entered 'mmHg'	System	12 Aug 2020 00:05:09

FDA-CBER-2022-1614-0508287

US3112192
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:08:42
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:01:30
User entered '74'	Matthew Musikanth (b) (4)	12 Aug 2020 00:05:09

US3112192
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:08:42
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User entered 'mmHg'	System	12 Aug 2020 00:05:09

US3112192
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 09 Jun 2021 15:08:42
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:01:30
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	12 Aug 2020 00:05:22

US3112192
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 09 Jun 2021 15:08:42
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:01:30
User entered '11 Aug 2020'	Matthew Musikanth (b) (4)	12 Aug 2020 00:05:22

FDA-CBER-2022-1614-0508291

US3112192
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:08:42
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:01:30
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	11 Aug 2020 19:55:55

US3112192
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:08:42
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:01:30
User entered empty.	Matthew Musikanth (b) (4)	11 Aug 2020 19:55:55

FDA-CBER-2022-1614-0508293

US3112192
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:08:42
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:01:30
User entered empty.	Matthew Musikanth (b) (4)	11 Aug 2020 19:55:55

US3112192
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:08:42
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User entered 'MRNA-1273 OR PLACEBO'	System	11 Aug 2020 19:55:55

US3112192
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:08:42
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:01:30
User entered '11 Aug 2020'	Matthew Musikanth (b) (4)	11 Aug 2020 19:55:55

FDA-CBER-2022-1614-0508296

US3112192
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:08:42
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:01:30
User entered '12:48'	Matthew Musikanth (b) (4)	11 Aug 2020 19:55:55

US3112192
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:08:42
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User entered '11 Aug 2020 12:48'	System	11 Aug 2020 19:55:55

US3112192
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:08:42
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:01:30
User entered 'Right Arm (RIGHT ARM)'	Matthew Musikanth (b) (4)	11 Aug 2020 19:55:55

FDA-CBER-2022-1614-0508299

US3112192
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:08:42
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User entered 'ONCE'	System	11 Aug 2020 19:55:55

US3112192
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 15:08:42
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User entered 'INTRAMUSCULAR'	System	11 Aug 2020 19:55:55

US3112192
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:08:42
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	12 Aug 2020 00:05:35

US3112192
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:08:42
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:01:30
User entered '11 Aug 2020'	Matthew Musikanth (b) (4)	12 Aug 2020 00:05:35

FDA-CBER-2022-1614-0508303

US3112192
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:08:42
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered '12:28'	Matthew Musikanth (b) (4)	12 Aug 2020 00:05:35

US3112192
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:08:42
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User entered '11 Aug 2020 12:28'	System	12 Aug 2020 00:05:35

US3112192
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 09 Jun 2021 15:08:42
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:01:30
User entered '11 Aug 2020'	Matthew Musikanth (b) (4)	12 Aug 2020 00:05:56

US3112192
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 15:08:42
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Matthew Musikanth (b) (4)	12 Aug 2020 00:05:56

US3112192
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 15:08:42
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	12 Aug 2020 00:05:56

US3112192
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 15:08:42
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered '12:22'	Matthew Musikanth (b) (4)	12 Aug 2020 00:05:56

US3112192
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 15:08:42
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User entered '11 Aug 2020 12:22'	System	12 Aug 2020 00:05:56

US3112192
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 15:08:42
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Matthew Musikanth (b) (4)	12 Aug 2020 00:05:56

US3112192
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 15:08:42
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered 'No (N)'	Matthew Musikanth (b) (4)	12 Aug 2020 00:05:56

US3112192
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 15:08:42
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:01:30
User entered empty.	Matthew Musikanth (b) (4)	12 Aug 2020 00:05:56

FDA-CBER-2022-1614-0508313

US3112192
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 15:08:42
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User entered empty.	System	12 Aug 2020 00:05:56

US3112192
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 09 Jun 2021 15:08:42
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:01:30
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	12 Aug 2020 00:06:01

FDA-CBER-2022-1614-0508315

US3112192
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 09 Jun 2021 15:08:42
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User entered '1'	System	12 Aug 2020 00:06:01

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	11 Aug 2020 19:55:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 19:55:55

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:08:42
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-11T13:21:41', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '31b49eec-98f6-45f8-872a-ec624a84f37e'	System	11 Aug 2020 20:22:11
User entered 'Yes (Y)'	System	11 Aug 2020 20:22:11

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:08:42
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-11T13:21:53', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '31b49eec-98f6-45f8-872a-ec624a84f37e'	System	11 Aug 2020 20:22:11
User entered '99.1'	System	11 Aug 2020 20:22:11

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:08:42
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-11T13:21:57', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '31b49eec-98f6-45f8-872a-ec624a84f37e'	System	11 Aug 2020 20:22:11
User entered 'No (N)'	System	11 Aug 2020 20:22:11

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:08:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-11T13:22:06', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '31b49eec-98f6-45f8-872a-ec624a84f37e'	System	11 Aug 2020 20:22:11
User entered '11 Aug 2020 13:22'	System	11 Aug 2020 20:22:11

FDA-CBER-2022-1614-0508321

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '11 Aug 2020 13:08'	System	11 Aug 2020 19:55:55

FDA-CBER-2022-1614-0508322

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '11 Aug 2020 15:38'	System	11 Aug 2020 19:55:55

FDA-CBER-2022-1614-0508323

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	11 Aug 2020 19:55:55
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 19:55:55

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:08:42
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-11T19:57:43', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '7e290512-a802-424c-9ebc-ecf9611f7229'	System	12 Aug 2020 03:00:09
User entered 'Yes (Y)'	System	12 Aug 2020 03:00:09

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:08:42
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-11T19:59:11', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '7e290512-a802-424c-9ebc-ecf9611f7229'	System	12 Aug 2020 03:00:09
User entered '98.5'	System	12 Aug 2020 03:00:09

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:08:42
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-11T19:59:35', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '7e290512-a802-424c-9ebc-ecf9611f7229'	System	12 Aug 2020 03:00:09
User entered 'Yes (Y)'	System	12 Aug 2020 03:00:09

FDA-CBER-2022-1614-0508327

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:08:42
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	29 Sep 2020 19:30:16
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	Karen Mylerberg (b) (4) (b) (4)	25 Sep 2020 19:56:22
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	12 Aug 2020 03:00:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-11T19:59:46', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '7e290512-a802-424c-9ebc-ecf9611f7229'	System	12 Aug 2020 03:00:09
User entered '1'	System	12 Aug 2020 03:00:09

FDA-CBER-2022-1614-0508328

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:08:42
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-11T19:59:46', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '7e290512-a802-424c-9ebc-ecf9611f7229'	System	12 Aug 2020 03:00:09
User entered '0'	System	12 Aug 2020 03:00:09

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:08:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-11T20:00:07', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '7e290512-a802-424c-9ebc-ecf9611f7229'	System	12 Aug 2020 03:00:09
User entered '11 Aug 2020 20:00'	System	12 Aug 2020 03:00:09

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '11 Aug 2020 16:33'	System	11 Aug 2020 19:55:55

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 19:55:55

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	11 Aug 2020 19:55:55
User entered 'Day 2'	System	11 Aug 2020 19:55:55

FDA-CBER-2022-1614-0508333

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:08:42
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-12T14:38:34', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'eef2b2f2-3613-439b-827c-96ac23222377'	System	12 Aug 2020 21:39:19
User entered 'Yes (Y)'	System	12 Aug 2020 21:39:19

FDA-CBER-2022-1614-0508334

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:08:42
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-12T14:38:43', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'eef2b2f2-3613-439b-827c-96ac23222377'	System	12 Aug 2020 21:39:19
User entered '98.6'	System	12 Aug 2020 21:39:19

FDA-CBER-2022-1614-0508335

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:08:42
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-12T14:38:49', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'eef2b2f2-3613-439b-827c-96ac23222377'	System	12 Aug 2020 21:39:19
User entered 'Yes (Y)'	System	12 Aug 2020 21:39:19

FDA-CBER-2022-1614-0508336

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:08:42
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	29 Sep 2020 19:32:22
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	Karen Mylerberg (b) (4) (b) (4)	25 Sep 2020 19:56:40
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	12 Aug 2020 21:39:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-12T14:38:58', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'eef2b2f2-3613-439b-827c-96ac23222377'	System	12 Aug 2020 21:39:19
User entered '1'	System	12 Aug 2020 21:39:19

FDA-CBER-2022-1614-0508337

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:08:42
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-12T14:38:58', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'eef2b2f2-3613-439b-827c-96ac23222377'	System	12 Aug 2020 21:39:19
User entered '0'	System	12 Aug 2020 21:39:19

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:08:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-12T14:39:14', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'eef2b2f2-3613-439b-827c-96ac23222377'	System	12 Aug 2020 21:39:19
User entered '12 Aug 2020 14:39'	System	12 Aug 2020 21:39:19

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 19:55:55

FDA-CBER-2022-1614-0508340

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 19:55:55

FDA-CBER-2022-1614-0508341

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	11 Aug 2020 19:55:55
User entered 'Day 3'	System	11 Aug 2020 19:55:55

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:08:42
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-13T22:26:29', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '9b12aa29-733b-41b9-98ee-12866c19db6a'	System	14 Aug 2020 05:27:27
User entered 'Yes (Y)'	System	14 Aug 2020 05:27:27

FDA-CBER-2022-1614-0508343

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:08:42
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-13T22:26:46', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '9b12aa29-733b-41b9-98ee-12866c19db6a'	System	14 Aug 2020 05:27:27
User entered '98.8'	System	14 Aug 2020 05:27:27

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:08:42
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-13T22:26:56', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '9b12aa29-733b-41b9-98ee-12866c19db6a'	System	14 Aug 2020 05:27:27
User entered 'Yes (Y)'	System	14 Aug 2020 05:27:27

FDA-CBER-2022-1614-0508345

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:08:42
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	29 Sep 2020 19:32:28
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	Karen Mylerberg (b) (4) (b) (4)	25 Sep 2020 19:56:52
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	14 Aug 2020 05:27:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-13T22:27:17', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '9b12aa29-733b-41b9-98ee-12866c19db6a'	System	14 Aug 2020 05:27:27
User entered '1'	System	14 Aug 2020 05:27:27

FDA-CBER-2022-1614-0508346

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:08:42
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-13T22:27:17', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '9b12aa29-733b-41b9-98ee-12866c19db6a'	System	14 Aug 2020 05:27:27
User entered '0'	System	14 Aug 2020 05:27:27

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:08:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-13T22:27:24', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '9b12aa29-733b-41b9-98ee-12866c19db6a'	System	14 Aug 2020 05:27:27
User entered '13 Aug 2020 22:27'	System	14 Aug 2020 05:27:27

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 19:55:55

FDA-CBER-2022-1614-0508349

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 19:55:55

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	11 Aug 2020 19:55:55
User entered 'Day 4'	System	11 Aug 2020 19:55:55

FDA-CBER-2022-1614-0508351

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:08:42
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0508352

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:08:42
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0508353

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:08:42
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:08:42
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0508355

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:08:42
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0508356

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:08:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0508357

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 19:55:55

FDA-CBER-2022-1614-0508358

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 19:55:55

FDA-CBER-2022-1614-0508359

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	11 Aug 2020 19:55:55
User entered 'Day 5'	System	11 Aug 2020 19:55:55

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:08:42
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-15T16:26:54', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '705c9490-b6b9-4fcf-bf76-6a531620412b'	System	15 Aug 2020 23:27:33
User entered 'Yes (Y)'	System	15 Aug 2020 23:27:33

FDA-CBER-2022-1614-0508361

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:08:42
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-15T16:27:03', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '705c9490-b6b9-4fcf-bf76-6a531620412b'	System	15 Aug 2020 23:27:33
User entered '97.5'	System	15 Aug 2020 23:27:33

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:08:42
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-15T16:27:18', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '705c9490-b6b9-4fcf-bf76-6a531620412b'	System	15 Aug 2020 23:27:33
User entered 'No (N)'	System	15 Aug 2020 23:27:33

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:08:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-15T16:27:26', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '705c9490-b6b9-4fcf-bf76-6a531620412b'	System	15 Aug 2020 23:27:33
User entered '15 Aug 2020 16:27'	System	15 Aug 2020 23:27:33

FDA-CBER-2022-1614-0508364

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 19:55:55

FDA-CBER-2022-1614-0508365

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 19:55:55

FDA-CBER-2022-1614-0508366

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	11 Aug 2020 19:55:55
User entered 'Day 6'	System	11 Aug 2020 19:55:55

FDA-CBER-2022-1614-0508367

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:08:42
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-17T09:24:10', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'dfe6b62e-fdc4-4ebf-81a0-1e79a4e5de73'	System	17 Aug 2020 16:24:42
User entered 'Yes (Y)'	System	17 Aug 2020 16:24:42

FDA-CBER-2022-1614-0508368

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:08:42
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-17T09:24:22', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'dfe6b62e-fdc4-4ebf-81a0-1e79a4e5de73'	System	17 Aug 2020 16:24:42
User entered '98.9'	System	17 Aug 2020 16:24:42

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:08:42
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-17T09:24:33', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'dfe6b62e-fdc4-4ebf-81a0-1e79a4e5de73'	System	17 Aug 2020 16:24:42
User entered 'No (N)'	System	17 Aug 2020 16:24:42

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:08:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-17T09:24:39', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'dfe6b62e-fdc4-4ebf-81a0-1e79a4e5de73'	System	17 Aug 2020 16:24:42
User entered '17 Aug 2020 09:24'	System	17 Aug 2020 16:24:42

FDA-CBER-2022-1614-0508371

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 19:55:55

FDA-CBER-2022-1614-0508372

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 19:55:55

FDA-CBER-2022-1614-0508373

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	11 Aug 2020 19:55:55
User entered 'Day 7'	System	11 Aug 2020 19:55:55

FDA-CBER-2022-1614-0508374

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:08:42
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-18T11:06:33', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'faf3ef06-131f-4206-9c09-be75c21742d0'	System	18 Aug 2020 18:07:07
User entered 'Yes (Y)'	System	18 Aug 2020 18:07:07

FDA-CBER-2022-1614-0508375

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:08:42
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-18T11:06:47', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'faf3ef06-131f-4206-9c09-be75c21742d0'	System	18 Aug 2020 18:07:07
User entered '98.6'	System	18 Aug 2020 18:07:07

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:08:42
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-18T11:06:56', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'faf3ef06-131f-4206-9c09-be75c21742d0'	System	18 Aug 2020 18:07:07
User entered 'No (N)'	System	18 Aug 2020 18:07:07

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:08:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-18T11:07:04', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'faf3ef06-131f-4206-9c09-be75c21742d0'	System	18 Aug 2020 18:07:07
User entered '18 Aug 2020 11:07'	System	18 Aug 2020 18:07:07

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 19:55:55

FDA-CBER-2022-1614-0508379

US3112192
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 19:55:55

FDA-CBER-2022-1614-0508380

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	11 Aug 2020 19:55:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 19:55:55

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:08:42
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-11T13:23:56', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '8fac69aa-60e5-460a-a225-482709162f84'	System	11 Aug 2020 20:24:40
User entered 'None (1)'	System	11 Aug 2020 20:24:40

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:08:42
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-11T13:24:08', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '8fac69aa-60e5-460a-a225-482709162f84'	System	11 Aug 2020 20:24:40
User entered 'No (N)'	System	11 Aug 2020 20:24:40

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:08:42
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-11T13:24:15', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '8fac69aa-60e5-460a-a225-482709162f84'	System	11 Aug 2020 20:24:40
User entered 'No (N)'	System	11 Aug 2020 20:24:40

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:08:42
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-11T13:24:26', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '8fac69aa-60e5-460a-a225-482709162f84'	System	11 Aug 2020 20:24:40
User entered 'None (1)'	System	11 Aug 2020 20:24:40

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:08:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-11T13:24:34', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '8fac69aa-60e5-460a-a225-482709162f84'	System	11 Aug 2020 20:24:40
User entered '11 Aug 2020 13:24'	System	11 Aug 2020 20:24:40

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '11 Aug 2020 13:08'	System	11 Aug 2020 19:55:55

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '11 Aug 2020 15:38'	System	11 Aug 2020 19:55:55

FDA-CBER-2022-1614-0508388

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	11 Aug 2020 19:55:55
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 19:55:55

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:08:42
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-11T20:00:20', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '11924c4d-125e-4637-984e-53b8d53bcb28'	System	12 Aug 2020 03:00:53
User entered 'None (1)'	System	12 Aug 2020 03:00:53

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:08:42
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-11T20:00:26', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '11924c4d-125e-4637-984e-53b8d53bcb28'	System	12 Aug 2020 03:00:53
User entered 'No (N)'	System	12 Aug 2020 03:00:53

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:08:42
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-11T20:00:30', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '11924c4d-125e-4637-984e-53b8d53bcb28'	System	12 Aug 2020 03:00:53
User entered 'No (N)'	System	12 Aug 2020 03:00:53

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:08:42
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-11T20:00:40', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '11924c4d-125e-4637-984e-53b8d53bcb28'	System	12 Aug 2020 03:00:53
User entered 'None (1)'	System	12 Aug 2020 03:00:53

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:08:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-11T20:00:51', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '11924c4d-125e-4637-984e-53b8d53bcb28'	System	12 Aug 2020 03:00:53
User entered '11 Aug 2020 20:00'	System	12 Aug 2020 03:00:53

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '11 Aug 2020 16:33'	System	11 Aug 2020 19:55:55

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 19:55:55

FDA-CBER-2022-1614-0508396

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	11 Aug 2020 19:55:55
User entered 'Day 2'	System	11 Aug 2020 19:55:55

FDA-CBER-2022-1614-0508397

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:08:42
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-12T14:39:28', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '6785ad76-3200-4434-ae0c-b2056ae2b6c1'	System	12 Aug 2020 21:40:08
User entered 'None (1)'	System	12 Aug 2020 21:40:08

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:08:42
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-12T14:39:32', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '6785ad76-3200-4434-ae0c-b2056ae2b6c1'	System	12 Aug 2020 21:40:08
User entered 'No (N)'	System	12 Aug 2020 21:40:08

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:08:42
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-12T14:39:42', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '6785ad76-3200-4434-ae0c-b2056ae2b6c1'	System	12 Aug 2020 21:40:08
User entered 'No (N)'	System	12 Aug 2020 21:40:08

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:08:42
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-12T14:39:46', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '6785ad76-3200-4434-ae0c-b2056ae2b6c1'	System	12 Aug 2020 21:40:08
User entered 'None (1)'	System	12 Aug 2020 21:40:08

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:08:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-12T14:40:02', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '6785ad76-3200-4434-ae0c-b2056ae2b6c1'	System	12 Aug 2020 21:40:08
User entered '12 Aug 2020 14:40'	System	12 Aug 2020 21:40:08

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 19:55:55

FDA-CBER-2022-1614-0508403

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 19:55:55

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	11 Aug 2020 19:55:55
User entered 'Day 3'	System	11 Aug 2020 19:55:55

FDA-CBER-2022-1614-0508405

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:08:42
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-13T22:27:47', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '2eaab478-5f69-48cd-bfa3-324da5ce877d'	System	14 Aug 2020 05:28:11
User entered 'None (1)'	System	14 Aug 2020 05:28:11

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:08:42
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-13T22:27:50', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '2eaab478-5f69-48cd-bfa3-324da5ce877d'	System	14 Aug 2020 05:28:11
User entered 'No (N)'	System	14 Aug 2020 05:28:11

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:08:42
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-13T22:27:54', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '2eaab478-5f69-48cd-bfa3-324da5ce877d'	System	14 Aug 2020 05:28:11
User entered 'No (N)'	System	14 Aug 2020 05:28:11

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:08:42
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-13T22:28:01', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '2eaab478-5f69-48cd-bfa3-324da5ce877d'	System	14 Aug 2020 05:28:11
User entered 'None (1)'	System	14 Aug 2020 05:28:11

FDA-CBER-2022-1614-0508409

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:08:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-13T22:28:08', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '2eaab478-5f69-48cd-bfa3-324da5ce877d'	System	14 Aug 2020 05:28:11
User entered '13 Aug 2020 22:28'	System	14 Aug 2020 05:28:11

FDA-CBER-2022-1614-0508410

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 19:55:55

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 19:55:55

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	11 Aug 2020 19:55:55
User entered 'Day 4'	System	11 Aug 2020 19:55:55

FDA-CBER-2022-1614-0508413

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:08:42
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0508414

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:08:42
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:08:42
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)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0508416

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:08:42
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0508417

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:08:42
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)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0508418

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:08:42
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:08:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0508420

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 19:55:55

FDA-CBER-2022-1614-0508421

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 19:55:55

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	11 Aug 2020 19:55:55
User entered 'Day 5'	System	11 Aug 2020 19:55:55

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:08:42
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-15T16:27:33', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'fa25b522-bf6e-40ca-b186-7e65107e2233'	System	15 Aug 2020 23:28:04
User entered 'None (1)'	System	15 Aug 2020 23:28:04

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:08:42
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-15T16:27:36', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'fa25b522-bf6e-40ca-b186-7e65107e2233'	System	15 Aug 2020 23:28:04
User entered 'No (N)'	System	15 Aug 2020 23:28:04

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:08:42
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-15T16:27:41', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'fa25b522-bf6e-40ca-b186-7e65107e2233'	System	15 Aug 2020 23:28:04
User entered 'No (N)'	System	15 Aug 2020 23:28:04

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:08:42
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-15T16:27:52', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'fa25b522-bf6e-40ca-b186-7e65107e2233'	System	15 Aug 2020 23:28:04
User entered 'None (1)'	System	15 Aug 2020 23:28:04

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:08:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-15T16:27:58', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'fa25b522-bf6e-40ca-b186-7e65107e2233'	System	15 Aug 2020 23:28:04
User entered '15 Aug 2020 16:27'	System	15 Aug 2020 23:28:04

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 19:55:55

FDA-CBER-2022-1614-0508429

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 19:55:55

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	11 Aug 2020 19:55:55
User entered 'Day 6'	System	11 Aug 2020 19:55:55

FDA-CBER-2022-1614-0508431

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:08:42
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-17T09:22:59', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '6cd9c516-a034-470e-9b83-dfd84f8504ef'	System	17 Aug 2020 16:23:33
User entered 'None (1)'	System	17 Aug 2020 16:23:33

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:08:42
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-17T09:23:03', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '6cd9c516-a034-470e-9b83-dfd84f8504ef'	System	17 Aug 2020 16:23:33
User entered 'No (N)'	System	17 Aug 2020 16:23:33

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:08:42
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-17T09:23:06', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '6cd9c516-a034-470e-9b83-dfd84f8504ef'	System	17 Aug 2020 16:23:33
User entered 'No (N)'	System	17 Aug 2020 16:23:33

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:08:42
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-17T09:23:10', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '6cd9c516-a034-470e-9b83-dfd84f8504ef'	System	17 Aug 2020 16:23:33
User entered 'None (1)'	System	17 Aug 2020 16:23:33

FDA-CBER-2022-1614-0508435

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:08:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-17T09:23:23', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '6cd9c516-a034-470e-9b83-dfd84f8504ef'	System	17 Aug 2020 16:23:33
User entered '17 Aug 2020 09:23'	System	17 Aug 2020 16:23:33

FDA-CBER-2022-1614-0508436

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 19:55:55

FDA-CBER-2022-1614-0508437

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 19:55:55

FDA-CBER-2022-1614-0508438

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	11 Aug 2020 19:55:55
User entered 'Day 7'	System	11 Aug 2020 19:55:55

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:08:42
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-18T11:07:12', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'bcba27de-88ec-4179-ae3f-1c8f1a5fea58'	System	18 Aug 2020 18:07:59
User entered 'None (1)'	System	18 Aug 2020 18:07:59

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:08:42
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-18T11:07:17', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'bcba27de-88ec-4179-ae3f-1c8f1a5fea58'	System	18 Aug 2020 18:07:59
User entered 'No (N)'	System	18 Aug 2020 18:07:59

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:08:42
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-18T11:07:33', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'bcba27de-88ec-4179-ae3f-1c8f1a5fea58'	System	18 Aug 2020 18:07:59
User entered 'No (N)'	System	18 Aug 2020 18:07:59

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:08:42
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-18T11:07:45', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'bcba27de-88ec-4179-ae3f-1c8f1a5fea58'	System	18 Aug 2020 18:07:59
User entered 'None (1)'	System	18 Aug 2020 18:07:59

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:08:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-18T11:07:54', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'bcba27de-88ec-4179-ae3f-1c8f1a5fea58'	System	18 Aug 2020 18:07:59
User entered '18 Aug 2020 11:07'	System	18 Aug 2020 18:07:59

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 19:55:55

FDA-CBER-2022-1614-0508445

US3112192
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 19:55:55

FDA-CBER-2022-1614-0508446

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	11 Aug 2020 19:55:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 19:55:55

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:08:42
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-11T13:22:23', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '29197515-6223-4677-b076-93530ac30f64'	System	11 Aug 2020 20:23:51
User entered 'None (0)'	System	11 Aug 2020 20:23:51

FDA-CBER-2022-1614-0508448

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:08:42
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-11T13:22:28', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '29197515-6223-4677-b076-93530ac30f64'	System	11 Aug 2020 20:23:51
User entered 'None (0)'	System	11 Aug 2020 20:23:51

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:08:42
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-11T13:22:33', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '29197515-6223-4677-b076-93530ac30f64'	System	11 Aug 2020 20:23:51
User entered 'None (0)'	System	11 Aug 2020 20:23:51

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:08:42
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-11T13:22:41', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '29197515-6223-4677-b076-93530ac30f64'	System	11 Aug 2020 20:23:51
User entered 'None (0)'	System	11 Aug 2020 20:23:51

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:08:42
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-11T13:23:04', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '29197515-6223-4677-b076-93530ac30f64'	System	11 Aug 2020 20:23:51
User entered 'None (0)'	System	11 Aug 2020 20:23:51

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:08:42
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-11T13:23:14', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '29197515-6223-4677-b076-93530ac30f64'	System	11 Aug 2020 20:23:51
User entered 'None (0)'	System	11 Aug 2020 20:23:51

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:08:42
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-11T13:23:28', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '29197515-6223-4677-b076-93530ac30f64'	System	11 Aug 2020 20:23:51
User entered 'No (N)'	System	11 Aug 2020 20:23:51

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-11T13:23:44', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '29197515-6223-4677-b076-93530ac30f64'	System	11 Aug 2020 20:23:51
User entered '11 Aug 2020 13:23'	System	11 Aug 2020 20:23:51

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '11 Aug 2020 13:08'	System	11 Aug 2020 19:55:55

FDA-CBER-2022-1614-0508456

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '11 Aug 2020 15:38'	System	11 Aug 2020 19:55:55

FDA-CBER-2022-1614-0508457

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	11 Aug 2020 19:55:55
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 19:55:55

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:08:42
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-11T20:01:08', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'f8222440-f30b-41f7-8ce9-0d1836b50bb4'	System	12 Aug 2020 03:02:06
User entered 'None (0)'	System	12 Aug 2020 03:02:06

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:08:42
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-11T20:01:20', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'f8222440-f30b-41f7-8ce9-0d1836b50bb4'	System	12 Aug 2020 03:02:06
User entered 'No interference with activity (1)'	System	12 Aug 2020 03:02:06

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:08:42
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-11T20:01:28', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'f8222440-f30b-41f7-8ce9-0d1836b50bb4'	System	12 Aug 2020 03:02:06
User entered 'None (0)'	System	12 Aug 2020 03:02:06

FDA-CBER-2022-1614-0508461

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:08:42
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-11T20:01:31', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'f8222440-f30b-41f7-8ce9-0d1836b50bb4'	System	12 Aug 2020 03:02:06
User entered 'None (0)'	System	12 Aug 2020 03:02:06

FDA-CBER-2022-1614-0508462

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:08:42
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-11T20:01:36', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'f8222440-f30b-41f7-8ce9-0d1836b50bb4'	System	12 Aug 2020 03:02:06
User entered 'None (0)'	System	12 Aug 2020 03:02:06

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:08:42
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-11T20:01:40', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'f8222440-f30b-41f7-8ce9-0d1836b50bb4'	System	12 Aug 2020 03:02:06
User entered 'None (0)'	System	12 Aug 2020 03:02:06

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:08:42
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-11T20:01:49', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'f8222440-f30b-41f7-8ce9-0d1836b50bb4'	System	12 Aug 2020 03:02:06
User entered 'No (N)'	System	12 Aug 2020 03:02:06

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-11T20:02:02', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'f8222440-f30b-41f7-8ce9-0d1836b50bb4'	System	12 Aug 2020 03:02:06
User entered '11 Aug 2020 20:02'	System	12 Aug 2020 03:02:06

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '11 Aug 2020 16:33'	System	11 Aug 2020 19:55:55

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 19:55:55

FDA-CBER-2022-1614-0508468

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	11 Aug 2020 19:55:55
User entered 'Day 2'	System	11 Aug 2020 19:55:55

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:08:42
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-12T14:40:21', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '48f8a209-98cd-430d-bb89-e4293d73f365'	System	12 Aug 2020 21:41:51
User entered 'No interference with activity (1)'	System	12 Aug 2020 21:41:51

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:08:42
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-12T14:40:34', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '48f8a209-98cd-430d-bb89-e4293d73f365'	System	12 Aug 2020 21:41:51
User entered 'No interference with activity (1)'	System	12 Aug 2020 21:41:51

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:08:42
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-12T14:40:46', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '48f8a209-98cd-430d-bb89-e4293d73f365'	System	12 Aug 2020 21:41:51
User entered 'Some interference with activity (2)'	System	12 Aug 2020 21:41:51

FDA-CBER-2022-1614-0508472

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:08:42
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-12T14:40:57', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '48f8a209-98cd-430d-bb89-e4293d73f365'	System	12 Aug 2020 21:41:51
User entered 'Some interference with activity (2)'	System	12 Aug 2020 21:41:51

FDA-CBER-2022-1614-0508473

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:08:42
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-12T14:41:01', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '48f8a209-98cd-430d-bb89-e4293d73f365'	System	12 Aug 2020 21:41:51
User entered 'None (0)'	System	12 Aug 2020 21:41:51

FDA-CBER-2022-1614-0508474

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:08:42
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-12T14:41:04', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '48f8a209-98cd-430d-bb89-e4293d73f365'	System	12 Aug 2020 21:41:51
User entered 'None (0)'	System	12 Aug 2020 21:41:51

FDA-CBER-2022-1614-0508475

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:08:42
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-12T14:41:09', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '48f8a209-98cd-430d-bb89-e4293d73f365'	System	12 Aug 2020 21:41:51
User entered 'No (N)'	System	12 Aug 2020 21:41:51

FDA-CBER-2022-1614-0508476

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-12T14:41:30', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '48f8a209-98cd-430d-bb89-e4293d73f365'	System	12 Aug 2020 21:41:51
User entered '12 Aug 2020 14:41'	System	12 Aug 2020 21:41:51

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 19:55:55

FDA-CBER-2022-1614-0508478

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 19:55:55

FDA-CBER-2022-1614-0508479

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	11 Aug 2020 19:55:55
User entered 'Day 3'	System	11 Aug 2020 19:55:55

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:08:42
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-13T22:28:29', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '2de23b6d-e9e7-408b-98d2-ee124688b419'	System	14 Aug 2020 05:29:24
User entered 'None (0)'	System	14 Aug 2020 05:29:24

FDA-CBER-2022-1614-0508481

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:08:42
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-13T22:28:38', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '2de23b6d-e9e7-408b-98d2-ee124688b419'	System	14 Aug 2020 05:29:24
User entered 'No interference with activity (1)'	System	14 Aug 2020 05:29:24

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:08:42
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-13T22:28:50', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '2de23b6d-e9e7-408b-98d2-ee124688b419'	System	14 Aug 2020 05:29:24
User entered 'No interference with activity (1)'	System	14 Aug 2020 05:29:24

FDA-CBER-2022-1614-0508483

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:08:42
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-13T22:28:56', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '2de23b6d-e9e7-408b-98d2-ee124688b419'	System	14 Aug 2020 05:29:24
User entered 'None (0)'	System	14 Aug 2020 05:29:24

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:08:42
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-13T22:29:00', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '2de23b6d-e9e7-408b-98d2-ee124688b419'	System	14 Aug 2020 05:29:24
User entered 'None (0)'	System	14 Aug 2020 05:29:24

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:08:42
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-13T22:29:03', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '2de23b6d-e9e7-408b-98d2-ee124688b419'	System	14 Aug 2020 05:29:24
User entered 'None (0)'	System	14 Aug 2020 05:29:24

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:08:42
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-13T22:29:15', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '2de23b6d-e9e7-408b-98d2-ee124688b419'	System	14 Aug 2020 05:29:24
User entered 'No (N)'	System	14 Aug 2020 05:29:24

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-13T22:29:20', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '2de23b6d-e9e7-408b-98d2-ee124688b419'	System	14 Aug 2020 05:29:24
User entered '13 Aug 2020 22:29'	System	14 Aug 2020 05:29:24

FDA-CBER-2022-1614-0508488

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 19:55:55

FDA-CBER-2022-1614-0508489

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 19:55:55

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	11 Aug 2020 19:55:55
User entered 'Day 4'	System	11 Aug 2020 19:55:55

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:08:42
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0508492

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:08:42
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0508493

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:08:42
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0508494

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:08:42
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:08:42
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0508496

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:08:42
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0508497

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:08:42
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0508499

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 19:55:55

FDA-CBER-2022-1614-0508500

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 19:55:55

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	11 Aug 2020 19:55:55
User entered 'Day 5'	System	11 Aug 2020 19:55:55

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:08:42
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-15T16:28:07', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '199b3e67-5392-4197-be36-642b95534c4d'	System	15 Aug 2020 23:29:03
User entered 'None (0)'	System	15 Aug 2020 23:29:03

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:08:42
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-15T16:28:13', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '199b3e67-5392-4197-be36-642b95534c4d'	System	15 Aug 2020 23:29:03
User entered 'None (0)'	System	15 Aug 2020 23:29:03

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:08:42
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-15T16:28:23', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '199b3e67-5392-4197-be36-642b95534c4d'	System	15 Aug 2020 23:29:03
User entered 'No interference with activity (1)'	System	15 Aug 2020 23:29:03

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:08:42
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-15T16:28:31', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '199b3e67-5392-4197-be36-642b95534c4d'	System	15 Aug 2020 23:29:03
User entered 'No interference with activity (1)'	System	15 Aug 2020 23:29:03

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:08:42
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-15T16:28:45', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '199b3e67-5392-4197-be36-642b95534c4d'	System	15 Aug 2020 23:29:03
User entered 'None (0)'	System	15 Aug 2020 23:29:03

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:08:42
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-15T16:28:48', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '199b3e67-5392-4197-be36-642b95534c4d'	System	15 Aug 2020 23:29:03
User entered 'None (0)'	System	15 Aug 2020 23:29:03

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:08:42
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-15T16:28:52', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '199b3e67-5392-4197-be36-642b95534c4d'	System	15 Aug 2020 23:29:03
User entered 'No (N)'	System	15 Aug 2020 23:29:03

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-15T16:28:59', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '199b3e67-5392-4197-be36-642b95534c4d'	System	15 Aug 2020 23:29:03
User entered '15 Aug 2020 16:28'	System	15 Aug 2020 23:29:03

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 19:55:55

FDA-CBER-2022-1614-0508511

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 19:55:55

FDA-CBER-2022-1614-0508512

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	11 Aug 2020 19:55:55
User entered 'Day 6'	System	11 Aug 2020 19:55:55

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:08:42
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-17T09:25:04', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'e8cf4c91-32a3-4a33-9faf-f51131ac6cbd'	System	17 Aug 2020 16:25:58
User entered 'None (0)'	System	17 Aug 2020 16:25:58

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:08:42
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-17T09:25:11', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'e8cf4c91-32a3-4a33-9faf-f51131ac6cbd'	System	17 Aug 2020 16:25:58
User entered 'None (0)'	System	17 Aug 2020 16:25:58

FDA-CBER-2022-1614-0508515

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:08:42
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-17T09:25:19', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'e8cf4c91-32a3-4a33-9faf-f51131ac6cbd'	System	17 Aug 2020 16:25:58
User entered 'No interference with activity (1)'	System	17 Aug 2020 16:25:58

FDA-CBER-2022-1614-0508516

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:08:42
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-17T09:25:27', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'e8cf4c91-32a3-4a33-9faf-f51131ac6cbd'	System	17 Aug 2020 16:25:58
User entered 'No interference with activity (1)'	System	17 Aug 2020 16:25:58

FDA-CBER-2022-1614-0508517

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:08:42
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-17T09:25:31', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'e8cf4c91-32a3-4a33-9faf-f51131ac6cbd'	System	17 Aug 2020 16:25:58
User entered 'None (0)'	System	17 Aug 2020 16:25:58

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:08:42
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-17T09:25:37', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'e8cf4c91-32a3-4a33-9faf-f51131ac6cbd'	System	17 Aug 2020 16:25:58
User entered 'None (0)'	System	17 Aug 2020 16:25:58

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:08:42
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-17T09:25:44', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'e8cf4c91-32a3-4a33-9faf-f51131ac6cbd'	System	17 Aug 2020 16:25:58
User entered 'No (N)'	System	17 Aug 2020 16:25:58

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-17T09:25:56', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'e8cf4c91-32a3-4a33-9faf-f51131ac6cbd'	System	17 Aug 2020 16:25:58
User entered '17 Aug 2020 09:25'	System	17 Aug 2020 16:25:58

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 19:55:55

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 19:55:55

FDA-CBER-2022-1614-0508523

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	11 Aug 2020 19:55:55
User entered 'Day 7'	System	11 Aug 2020 19:55:55

FDA-CBER-2022-1614-0508524

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:08:42
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-18T11:08:09', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '1252beac-e6bf-42ad-8510-4c9764b1bf21'	System	18 Aug 2020 18:08:55
User entered 'No interference with activity (1)'	System	18 Aug 2020 18:08:55

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:08:42
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-18T11:08:12', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '1252beac-e6bf-42ad-8510-4c9764b1bf21'	System	18 Aug 2020 18:08:55
User entered 'No interference with activity (1)'	System	18 Aug 2020 18:08:55

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:08:42
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-18T11:08:18', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '1252beac-e6bf-42ad-8510-4c9764b1bf21'	System	18 Aug 2020 18:08:55
User entered 'None (0)'	System	18 Aug 2020 18:08:55

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:08:42
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-18T11:08:27', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '1252beac-e6bf-42ad-8510-4c9764b1bf21'	System	18 Aug 2020 18:08:55
User entered 'None (0)'	System	18 Aug 2020 18:08:55

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:08:42
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-18T11:08:32', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '1252beac-e6bf-42ad-8510-4c9764b1bf21'	System	18 Aug 2020 18:08:55
User entered 'None (0)'	System	18 Aug 2020 18:08:55

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:08:42
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-18T11:08:35', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '1252beac-e6bf-42ad-8510-4c9764b1bf21'	System	18 Aug 2020 18:08:55
User entered 'None (0)'	System	18 Aug 2020 18:08:55

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:08:42
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-18T11:08:40', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '1252beac-e6bf-42ad-8510-4c9764b1bf21'	System	18 Aug 2020 18:08:55
User entered 'No (N)'	System	18 Aug 2020 18:08:55

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-18T11:08:49', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '1252beac-e6bf-42ad-8510-4c9764b1bf21'	System	18 Aug 2020 18:08:55
User entered '18 Aug 2020 11:08'	System	18 Aug 2020 18:08:55

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 19:55:55

FDA-CBER-2022-1614-0508533

US3112192
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 19:55:55

US3112192
Folder: Diary Dose 1 (1)
Form: Headache_Day(8)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	18 Aug 2020 18:08:55
User entered 'Day 8'	System	18 Aug 2020 18:08:55

US3112192
Folder: Diary Dose 1 (1)
Form: Headache_Day(8)
Generated On: 09 Jun 2021 15:08:42
Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-19T09:49:07', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '6a74a432-7ff3-4108-af2b-65cbff6041d3'	System	19 Aug 2020 16:49:15
User entered 'None (0)'	System	19 Aug 2020 16:49:15

US3112192
Folder: Diary Dose 1 (1)
Form: Headache_Day(8)
Generated On: 09 Jun 2021 15:08:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-19T09:49:13', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '6a74a432-7ff3-4108-af2b-65cbff6041d3'	System	19 Aug 2020 16:49:15
User entered '19 Aug 2020 09:49'	System	19 Aug 2020 16:49:15

US3112192
Folder: Diary Dose 1 (1)
Form: Headache_Day(8)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '18 Aug 2020 12:00'	System	18 Aug 2020 18:08:55

FDA-CBER-2022-1614-0508538

US3112192
Folder: Diary Dose 1 (1)
Form: Headache_Day(8)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '19 Aug 2020 11:59'	System	18 Aug 2020 18:08:55

FDA-CBER-2022-1614-0508539

US3112192
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(8)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	18 Aug 2020 18:08:55
User entered 'Day 8'	System	18 Aug 2020 18:08:55

US3112192
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(8)
Generated On: 09 Jun 2021 15:08:42
Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-19T09:49:27', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'b42516d1-fb80-4c31-b12d-a48d3d783e20'	System	19 Aug 2020 16:49:34
User entered 'None (0)'	System	19 Aug 2020 16:49:34

FDA-CBER-2022-1614-0508541

US3112192
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(8)
Generated On: 09 Jun 2021 15:08:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-19T09:49:31', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'b42516d1-fb80-4c31-b12d-a48d3d783e20'	System	19 Aug 2020 16:49:34
User entered '19 Aug 2020 09:49'	System	19 Aug 2020 16:49:34

US3112192
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(8)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '18 Aug 2020 12:00'	System	18 Aug 2020 18:08:55

FDA-CBER-2022-1614-0508543

US3112192
Folder: Diary Dose 1 (1)
Form: Fatigue_Day(8)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '19 Aug 2020 11:59'	System	18 Aug 2020 18:08:55

FDA-CBER-2022-1614-0508544

US3112192
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	17 Aug 2020 16:25:58
User entered 'Day 8'	System	17 Aug 2020 16:25:58

FDA-CBER-2022-1614-0508545

US3112192
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 09 Jun 2021 15:08:42
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-19T09:49:38', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '4e93a089-4b28-4981-a3f8-4309918a2345'	System	19 Aug 2020 16:49:46
User entered 'No (N)'	System	19 Aug 2020 16:49:46

FDA-CBER-2022-1614-0508546

US3112192
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ffbec4bd7d8230e8)', Time: '2020-08-19T09:49:43', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '4e93a089-4b28-4981-a3f8-4309918a2345'	System	19 Aug 2020 16:49:46
User entered '19 Aug 2020 09:49'	System	19 Aug 2020 16:49:46

US3112192
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 16:25:58

FDA-CBER-2022-1614-0508548

US3112192
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 16:25:58

FDA-CBER-2022-1614-0508549

US3112192
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:08:42
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:42:50
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	19 Aug 2020 23:35:57

US3112192
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:08:42
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:42:50
User entered '19 Aug 2020'	Matthew Musikanth (b) (4)	19 Aug 2020 23:35:57

FDA-CBER-2022-1614-0508551

US3112192
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:08:42
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:42:50
User entered 'Contact Made (CONTACT MADE)'	Matthew Musikanth (b) (4)	19 Aug 2020 23:35:57

FDA-CBER-2022-1614-0508552

US3112192
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:08:42
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:42:50
User entered empty.	Matthew Musikanth (b) (4)	19 Aug 2020 23:35:57

FDA-CBER-2022-1614-0508553

US3112192
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:08:42
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:42:50
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	19 Aug 2020 23:36:01

US3112192
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:08:42
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User entered '1'	System	19 Aug 2020 23:36:01

US3112192
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:08:42
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:42:27
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	25 Aug 2020 23:37:41

FDA-CBER-2022-1614-0508556

US3112192
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:08:42
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:42:27
User entered '25 Aug 2020'	Matthew Musikanth (b) (4)	25 Aug 2020 23:37:41

FDA-CBER-2022-1614-0508557

US3112192
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:08:42
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:42:27
User entered 'Contact Made (CONTACT MADE)'	Matthew Musikanth (b) (4)	25 Aug 2020 23:37:41

US3112192
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:08:42
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:42:27
User entered empty.	Matthew Musikanth (b) (4)	25 Aug 2020 23:37:41

US3112192
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:08:42
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:42:27
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	25 Aug 2020 23:37:45

FDA-CBER-2022-1614-0508560

US3112192
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:08:42
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User entered '1'	System	25 Aug 2020 23:37:45

FDA-CBER-2022-1614-0508561

US3112192
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:08:42
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:42:27
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	01 Sep 2020 20:54:45

FDA-CBER-2022-1614-0508562

US3112192
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:08:42
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:42:27
User entered '01 Sep 2020'	Matthew Musikanth (b) (4)	01 Sep 2020 20:54:45

US3112192
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:08:42
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:42:27
User entered 'Contact Made (CONTACT MADE)'	Matthew Musikanth (b) (4)	01 Sep 2020 20:54:45

US3112192
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:08:42
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:42:27
User entered empty.	Matthew Musikanth (b) (4)	01 Sep 2020 20:54:45

FDA-CBER-2022-1614-0508565

US3112192
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:08:42
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:42:27
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	01 Sep 2020 20:54:48

FDA-CBER-2022-1614-0508566

US3112192
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:08:42
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User entered '1'	System	01 Sep 2020 20:54:48

US3112192
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:08:42
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:01:30
User closed query 'Per CDM: For Visit 2, "Was this visit performed?" is recorded as 'Yes'. Please review and update vital sign dosing as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 14:57:51
Query 'Per CDM: For Visit 2, "Was this visit performed?" is recorded as 'Yes'. Please review and update vital sign dosing as appropriate.' answered with 'done' (Site from DM).	Nicolle Mendez (b) (4)	18 Sep 2020 19:58:13
User opened query 'Per CDM: For Visit 2, "Was this visit performed?" is recorded as 'Yes'. Please review and update vital sign dosing as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 15:27:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 18:02:56

US3112192
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:08:42
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:01:30
User entered '11 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 18:02:56

US3112192
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:08:42
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:01:30
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	11 Sep 2020 18:02:56

FDA-CBER-2022-1614-0508570

US3112192
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:08:42
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User entered 'VISIT2'	System	11 Sep 2020 18:02:56

FDA-CBER-2022-1614-0508571

US3112192
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:08:42
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User accepted default value 'Pre-Dose (PREDOSE)'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 18:58:12

US3112192
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:08:42
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered 'Yes (Y)'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 18:58:12

US3112192
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:08:42
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered '11 Sep 2020'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 18:58:12

FDA-CBER-2022-1614-0508574

US3112192
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:08:42
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered '09:13'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 18:58:12

FDA-CBER-2022-1614-0508575

US3112192
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:08:42
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User entered '11 Sep 2020 09:13'	System	18 Sep 2020 18:58:12

FDA-CBER-2022-1614-0508576

US3112192
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:08:42
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered '99.3' F	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 18:58:12

US3112192
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:08:42
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered 'Oral (Oral)'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 18:58:12

US3112192
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:08:42
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered empty.	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 18:58:12

US3112192
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:08:42
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered '49'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 18:58:12

FDA-CBER-2022-1614-0508580

US3112192
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:08:42
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User entered 'bpm'	System	18 Sep 2020 18:58:12

FDA-CBER-2022-1614-0508581

US3112192
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:08:42
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered '17'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 18:58:12

FDA-CBER-2022-1614-0508582

US3112192
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:08:42
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User entered 'breaths/min'	System	18 Sep 2020 18:58:12

US3112192
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:08:42
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered '138'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 18:58:12

FDA-CBER-2022-1614-0508584

US3112192
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:08:42
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User entered 'mmHg'	System	18 Sep 2020 18:58:12

FDA-CBER-2022-1614-0508585

US3112192
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:08:42
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered '66'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 18:58:12

FDA-CBER-2022-1614-0508586

US3112192
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:08:42
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User entered 'mmHg'	System	18 Sep 2020 18:58:12

US3112192
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:08:42
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User accepted default value 'Post-Dose (POSTDOSE)'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 18:58:41

US3112192
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:08:42
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered 'Yes (Y)'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 18:58:41

US3112192
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:08:42
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered '11 Sep 2020'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 18:58:41

US3112192
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:08:42
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered '11:20'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 18:58:41

FDA-CBER-2022-1614-0508591

US3112192
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:08:42
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User entered '11 Sep 2020 11:20'	System	18 Sep 2020 18:58:41

FDA-CBER-2022-1614-0508592

US3112192
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:08:42
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered '98.3' F	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 18:58:41

FDA-CBER-2022-1614-0508593

US3112192
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:08:42
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered 'Oral (Oral)'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 18:58:41

US3112192
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:08:42
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered empty.	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 18:58:41

US3112192
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:08:42
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered '60'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 18:58:41

FDA-CBER-2022-1614-0508596

US3112192
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:08:42
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User entered 'bpm'	System	18 Sep 2020 18:58:41

FDA-CBER-2022-1614-0508597

US3112192
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:08:42
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered '14'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 18:58:41

FDA-CBER-2022-1614-0508598

US3112192
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:08:42
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User entered 'breaths/min'	System	18 Sep 2020 18:58:41

FDA-CBER-2022-1614-0508599

US3112192
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:08:42
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered '118'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 18:58:41

US3112192
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:08:42
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User entered 'mmHg'	System	18 Sep 2020 18:58:41

FDA-CBER-2022-1614-0508601

US3112192
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:08:42
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered '66'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 18:58:41

US3112192
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:08:42
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User entered 'mmHg'	System	18 Sep 2020 18:58:41

FDA-CBER-2022-1614-0508603

US3112192
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 15:08:42
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered 'Yes (Y)'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 18:59:00

US3112192
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 15:08:42
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered '11 Sep 2020'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 18:59:00

FDA-CBER-2022-1614-0508605

US3112192
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:08:42
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:01:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 18:03:18

FDA-CBER-2022-1614-0508606

US3112192
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:08:42
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:01:30
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 18:03:18

FDA-CBER-2022-1614-0508607

US3112192
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:08:42
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:01:30
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 18:03:18

US3112192
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:08:42
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User entered 'MRNA-1273 OR PLACEBO'	System	11 Sep 2020 18:03:18

US3112192
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:08:42
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:01:30
User entered '11 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 18:03:18

US3112192
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:08:42
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:01:30
User entered '10:44'	(b) (4), (b) (6)	11 Sep 2020 18:03:18

FDA-CBER-2022-1614-0508611

US3112192
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:08:42
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User entered '11 Sep 2020 10:44'	System	11 Sep 2020 18:03:18

US3112192
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:08:42
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:01:30
User entered 'Right Arm (RIGHT ARM)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 18:03:18

FDA-CBER-2022-1614-0508613

US3112192
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:08:42
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User entered 'ONCE'	System	11 Sep 2020 18:03:18

US3112192
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:08:42
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User entered 'INTRAMUSCULAR'	System	11 Sep 2020 18:03:18

US3112192
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:08:42
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered 'Yes (Y)'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 18:59:18

US3112192
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:08:42
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered '11 Sep 2020'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 18:59:18

US3112192
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:08:42
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered '09:50'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 18:59:18

US3112192
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:08:42
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User entered '11 Sep 2020 09:50'	System	18 Sep 2020 18:59:18

US3112192
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 09 Jun 2021 15:08:42
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered '11 Sep 2020'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 18:59:32

US3112192
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 15:08:42
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 18:59:32

FDA-CBER-2022-1614-0508621

US3112192
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 15:08:42
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered 'Yes (Y)'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 18:59:32

US3112192
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 15:08:42
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered '09:37'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 18:59:32

FDA-CBER-2022-1614-0508623

US3112192
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 15:08:42
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User entered '11 Sep 2020 09:37'	System	18 Sep 2020 18:59:32

FDA-CBER-2022-1614-0508624

US3112192
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 15:08:42
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 18:59:32

US3112192
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 15:08:42
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered 'No (N)'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 18:59:32

US3112192
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 15:08:42
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered empty.	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 18:59:32

US3112192
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 15:08:42
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User entered empty.	System	18 Sep 2020 18:59:32

US3112192
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:08:42
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:01:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 18:03:26

US3112192
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:08:42
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User entered '1'	System	11 Sep 2020 18:03:26

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	11 Sep 2020 18:03:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 18:03:18

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:08:42
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-11T11:34:09', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '7917e025-7e08-4656-93cd-871affc06712'	System	11 Sep 2020 18:34:48
User entered 'Yes (Y)'	System	11 Sep 2020 18:34:48

FDA-CBER-2022-1614-0508632

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:08:42
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-11T11:34:24', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '7917e025-7e08-4656-93cd-871affc06712'	System	11 Sep 2020 18:34:48
User entered '98.3'	System	11 Sep 2020 18:34:48

FDA-CBER-2022-1614-0508633

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:08:42
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-11T11:34:34', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '7917e025-7e08-4656-93cd-871affc06712'	System	11 Sep 2020 18:34:48
User entered 'No (N)'	System	11 Sep 2020 18:34:48

FDA-CBER-2022-1614-0508634

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:08:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-11T11:34:45', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '7917e025-7e08-4656-93cd-871affc06712'	System	11 Sep 2020 18:34:48
User entered '11 Sep 2020 11:34'	System	11 Sep 2020 18:34:48

FDA-CBER-2022-1614-0508635

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '11 Sep 2020 11:04'	System	11 Sep 2020 18:03:18

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '11 Sep 2020 13:34'	System	11 Sep 2020 18:03:18

FDA-CBER-2022-1614-0508637

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	11 Sep 2020 18:03:18
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 18:03:18

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:08:42
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0508639

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:08:42
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0508640

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:08:42
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0508641

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:08:42
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0508642

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:08:42
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0508643

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:08:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0508644

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '11 Sep 2020 14:29'	System	11 Sep 2020 18:03:18

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 18:03:18

FDA-CBER-2022-1614-0508646

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	11 Sep 2020 18:03:18
User entered 'Day 2'	System	11 Sep 2020 18:03:18

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:08:42
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-12T21:50:17', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '3c52884a-8660-4171-bcff-daacc6239c2f'	System	13 Sep 2020 04:50:51
User entered 'Yes (Y)'	System	13 Sep 2020 04:50:51

FDA-CBER-2022-1614-0508648

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:08:42
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-12T21:50:23', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '3c52884a-8660-4171-bcff-daacc6239c2f'	System	13 Sep 2020 04:50:51
User entered '98.7'	System	13 Sep 2020 04:50:51

FDA-CBER-2022-1614-0508649

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:08:42
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-12T21:50:27', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '3c52884a-8660-4171-bcff-daacc6239c2f'	System	13 Sep 2020 04:50:51
User entered 'Yes (Y)'	System	13 Sep 2020 04:50:51

FDA-CBER-2022-1614-0508650

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:08:42
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	22 Sep 2020 14:56:33
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Confirmed with the patient that c-meds were taken for AE 1 and 2 and not for Solicited ARs' (Site from System).	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 20:07:19
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	13 Sep 2020 04:50:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-12T21:50:32', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '3c52884a-8660-4171-bcff-daacc6239c2f'	System	13 Sep 2020 04:50:51
User entered '1'	System	13 Sep 2020 04:50:51

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:08:42
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-12T21:50:32', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '3c52884a-8660-4171-bcff-daacc6239c2f'	System	13 Sep 2020 04:50:51
User entered '0'	System	13 Sep 2020 04:50:51

FDA-CBER-2022-1614-0508652

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:08:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-12T21:50:45', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '3c52884a-8660-4171-bcff-daacc6239c2f'	System	13 Sep 2020 04:50:51
User entered '12 Sep 2020 21:50'	System	13 Sep 2020 04:50:51

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 18:03:18

FDA-CBER-2022-1614-0508654

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 18:03:18

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	11 Sep 2020 18:03:18
User entered 'Day 3'	System	11 Sep 2020 18:03:18

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:08:42
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-13T23:19:40', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '16fc2b9e-2496-4dd6-9ac4-d14654bae274'	System	14 Sep 2020 06:20:27
User entered 'Yes (Y)'	System	14 Sep 2020 06:20:27

FDA-CBER-2022-1614-0508657

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:08:42
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-13T23:19:49', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '16fc2b9e-2496-4dd6-9ac4-d14654bae274'	System	14 Sep 2020 06:20:27
User entered '99.1'	System	14 Sep 2020 06:20:27

FDA-CBER-2022-1614-0508658

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:08:42
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-13T23:19:54', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '16fc2b9e-2496-4dd6-9ac4-d14654bae274'	System	14 Sep 2020 06:20:27
User entered 'Yes (Y)'	System	14 Sep 2020 06:20:27

FDA-CBER-2022-1614-0508659

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:08:42
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-13T23:20:12', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '16fc2b9e-2496-4dd6-9ac4-d14654bae274'	System	14 Sep 2020 06:20:27
User entered '0'	System	14 Sep 2020 06:20:27

FDA-CBER-2022-1614-0508660

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:08:42
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	22 Sep 2020 14:56:42
Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Confirmed with the patient that c-meds were taken for AE 1 and 2 and not for Solicited ARs' (Site from System).	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 20:07:25
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	14 Sep 2020 06:20:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-13T23:20:12', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '16fc2b9e-2496-4dd6-9ac4-d14654bae274'	System	14 Sep 2020 06:20:27
User entered '1'	System	14 Sep 2020 06:20:27

FDA-CBER-2022-1614-0508661

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:08:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-13T23:20:24', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '16fc2b9e-2496-4dd6-9ac4-d14654bae274'	System	14 Sep 2020 06:20:27
User entered '13 Sep 2020 23:20'	System	14 Sep 2020 06:20:27

FDA-CBER-2022-1614-0508662

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 18:03:18

FDA-CBER-2022-1614-0508663

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 18:03:18

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	11 Sep 2020 18:03:18
User entered 'Day 4'	System	11 Sep 2020 18:03:18

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:08:42
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-15T08:32:15', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'f2675040-b107-4a0b-9567-091a7151330a'	System	15 Sep 2020 15:33:00
User entered 'Yes (Y)'	System	15 Sep 2020 15:33:00

FDA-CBER-2022-1614-0508666

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:08:42
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-15T08:32:30', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'f2675040-b107-4a0b-9567-091a7151330a'	System	15 Sep 2020 15:33:00
User entered '99.6'	System	15 Sep 2020 15:33:00

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:08:42
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-15T08:32:34', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'f2675040-b107-4a0b-9567-091a7151330a'	System	15 Sep 2020 15:33:00
User entered 'Yes (Y)'	System	15 Sep 2020 15:33:00

FDA-CBER-2022-1614-0508668

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:08:42
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-15T08:32:41', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'f2675040-b107-4a0b-9567-091a7151330a'	System	15 Sep 2020 15:33:00
User entered '0'	System	15 Sep 2020 15:33:00

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:08:42
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	22 Sep 2020 14:56:48
Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Confirmed with the patient that c-meds were taken for AE 1 and 2 and not for Solicited ARs' (Site from System).	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 20:07:30
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	15 Sep 2020 15:33:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-15T08:32:41', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'f2675040-b107-4a0b-9567-091a7151330a'	System	15 Sep 2020 15:33:00
User entered '1'	System	15 Sep 2020 15:33:00

FDA-CBER-2022-1614-0508670

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:08:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-15T08:32:55', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'f2675040-b107-4a0b-9567-091a7151330a'	System	15 Sep 2020 15:33:00
User entered '15 Sep 2020 08:32'	System	15 Sep 2020 15:33:00

FDA-CBER-2022-1614-0508671

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 18:03:18

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 18:03:18

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	11 Sep 2020 18:03:18
User entered 'Day 5'	System	11 Sep 2020 18:03:18

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:08:42
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-15T13:46:00', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'd56dee77-77fe-444c-9589-8136da405f09'	System	15 Sep 2020 20:46:44
User entered 'Yes (Y)'	System	15 Sep 2020 20:46:44

FDA-CBER-2022-1614-0508675

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:08:42
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-15T13:46:11', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'd56dee77-77fe-444c-9589-8136da405f09'	System	15 Sep 2020 20:46:44
User entered '99.3'	System	15 Sep 2020 20:46:44

FDA-CBER-2022-1614-0508676

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:08:42
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-15T13:46:20', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'd56dee77-77fe-444c-9589-8136da405f09'	System	15 Sep 2020 20:46:44
User entered 'Yes (Y)'	System	15 Sep 2020 20:46:44

FDA-CBER-2022-1614-0508677

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:08:42
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	22 Sep 2020 14:56:54
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Confirmed with the patient that c-meds were taken for AE 1 and 2 and not for Solicited ARs' (Site from System).	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 20:07:35
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	15 Sep 2020 20:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-15T13:46:25', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'd56dee77-77fe-444c-9589-8136da405f09'	System	15 Sep 2020 20:46:44
User entered '1'	System	15 Sep 2020 20:46:44

FDA-CBER-2022-1614-0508678

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:08:42
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-15T13:46:25', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'd56dee77-77fe-444c-9589-8136da405f09'	System	15 Sep 2020 20:46:44
User entered '0'	System	15 Sep 2020 20:46:44

FDA-CBER-2022-1614-0508679

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:08:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-15T13:46:37', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'd56dee77-77fe-444c-9589-8136da405f09'	System	15 Sep 2020 20:46:44
User entered '15 Sep 2020 13:46'	System	15 Sep 2020 20:46:44

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 18:03:18

FDA-CBER-2022-1614-0508681

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 18:03:18

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	11 Sep 2020 18:03:18
User entered 'Day 6'	System	11 Sep 2020 18:03:18

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:08:42
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-16T15:25:17', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '6d9e2d01-6a95-4e24-9983-4c15b0f07126'	System	16 Sep 2020 22:25:53
User entered 'Yes (Y)'	System	16 Sep 2020 22:25:53

FDA-CBER-2022-1614-0508684

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:08:42
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-16T15:25:25', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '6d9e2d01-6a95-4e24-9983-4c15b0f07126'	System	16 Sep 2020 22:25:53
User entered '99.1'	System	16 Sep 2020 22:25:53

FDA-CBER-2022-1614-0508685

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:08:42
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-16T15:25:30', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '6d9e2d01-6a95-4e24-9983-4c15b0f07126'	System	16 Sep 2020 22:25:53
User entered 'Yes (Y)'	System	16 Sep 2020 22:25:53

FDA-CBER-2022-1614-0508686

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:08:42
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	22 Sep 2020 14:56:59
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Confirmed with the patient that c-meds were taken for AE 1 and 2 and not for Solicited ARs' (Site from System).	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 20:07:40
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	16 Sep 2020 22:25:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-16T15:25:35', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '6d9e2d01-6a95-4e24-9983-4c15b0f07126'	System	16 Sep 2020 22:25:53
User entered '1'	System	16 Sep 2020 22:25:53

FDA-CBER-2022-1614-0508687

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:08:42
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-16T15:25:35', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '6d9e2d01-6a95-4e24-9983-4c15b0f07126'	System	16 Sep 2020 22:25:53
User entered '0'	System	16 Sep 2020 22:25:53

FDA-CBER-2022-1614-0508688

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:08:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-16T15:25:46', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '6d9e2d01-6a95-4e24-9983-4c15b0f07126'	System	16 Sep 2020 22:25:53
User entered '16 Sep 2020 15:25'	System	16 Sep 2020 22:25:53

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 18:03:18

FDA-CBER-2022-1614-0508690

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 18:03:18

FDA-CBER-2022-1614-0508691

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	11 Sep 2020 18:03:18
User entered 'Day 7'	System	11 Sep 2020 18:03:18

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:08:42
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-17T12:52:26', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '97660f6b-e4cd-48b3-a6e6-ce0afc90f50f'	System	19 Sep 2020 07:58:02
User entered 'Yes (Y)'	System	19 Sep 2020 07:58:02

FDA-CBER-2022-1614-0508693

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:08:42
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-17T12:52:41', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '97660f6b-e4cd-48b3-a6e6-ce0afc90f50f'	System	19 Sep 2020 07:58:02
User entered '99.3'	System	19 Sep 2020 07:58:02

FDA-CBER-2022-1614-0508694

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:08:42
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-17T12:52:45', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '97660f6b-e4cd-48b3-a6e6-ce0afc90f50f'	System	19 Sep 2020 07:58:02
User entered 'Yes (Y)'	System	19 Sep 2020 07:58:02

FDA-CBER-2022-1614-0508695

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:08:42
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' canceled (Site from System).	(b) (4), (b) (6)	22 Sep 2020 14:57:05
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	19 Sep 2020 07:58:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-17T12:52:49', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '97660f6b-e4cd-48b3-a6e6-ce0afc90f50f'	System	19 Sep 2020 07:58:02
User entered '1'	System	19 Sep 2020 07:58:02

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:08:42
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-17T12:52:49', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '97660f6b-e4cd-48b3-a6e6-ce0afc90f50f'	System	19 Sep 2020 07:58:02
User entered '0'	System	19 Sep 2020 07:58:02

FDA-CBER-2022-1614-0508697

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:08:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-17T12:52:55', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '97660f6b-e4cd-48b3-a6e6-ce0afc90f50f'	System	19 Sep 2020 07:58:02
User entered '17 Sep 2020 12:52'	System	19 Sep 2020 07:58:02

FDA-CBER-2022-1614-0508698

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 18:03:18

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 18:03:18

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(8)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	16 Sep 2020 22:25:53
User entered 'Day 8'	System	16 Sep 2020 22:25:53

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(8)
Generated On: 09 Jun 2021 15:08:42
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-19T00:58:48', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '511e9545-6600-4abb-acad-e483f2a1eb32'	System	19 Sep 2020 07:59:37
User entered 'Yes (Y)'	System	19 Sep 2020 07:59:37

FDA-CBER-2022-1614-0508702

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(8)
Generated On: 09 Jun 2021 15:08:42
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-19T00:59:00', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '511e9545-6600-4abb-acad-e483f2a1eb32'	System	19 Sep 2020 07:59:37
User entered '98.3'	System	19 Sep 2020 07:59:37

FDA-CBER-2022-1614-0508703

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(8)
Generated On: 09 Jun 2021 15:08:42
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-19T00:59:14', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '511e9545-6600-4abb-acad-e483f2a1eb32'	System	19 Sep 2020 07:59:37
User entered 'Yes (Y)'	System	19 Sep 2020 07:59:37

FDA-CBER-2022-1614-0508704

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(8)
Generated On: 09 Jun 2021 15:08:42
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	29 Sep 2020 19:32:49
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	Karen Mylerberg (b) (4) (b) (4)	25 Sep 2020 20:01:06
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	19 Sep 2020 07:59:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-19T00:59:20', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '511e9545-6600-4abb-acad-e483f2a1eb32'	System	19 Sep 2020 07:59:37
User entered '1'	System	19 Sep 2020 07:59:37

FDA-CBER-2022-1614-0508705

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(8)
Generated On: 09 Jun 2021 15:08:42
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-19T00:59:20', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '511e9545-6600-4abb-acad-e483f2a1eb32'	System	19 Sep 2020 07:59:37
User entered '0'	System	19 Sep 2020 07:59:37

FDA-CBER-2022-1614-0508706

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(8)
Generated On: 09 Jun 2021 15:08:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-19T00:59:34', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '511e9545-6600-4abb-acad-e483f2a1eb32'	System	19 Sep 2020 07:59:37
User entered '19 Sep 2020 00:59'	System	19 Sep 2020 07:59:37

FDA-CBER-2022-1614-0508707

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(8)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 22:25:53

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(8)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 22:25:53

FDA-CBER-2022-1614-0508709

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(9)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	19 Sep 2020 07:58:02
User entered 'Day 9'	System	19 Sep 2020 07:58:02

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(9)
Generated On: 09 Jun 2021 15:08:42
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-19T18:55:57', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'fa2a02ec-8b83-417e-9338-61cb7c8b75aa'	System	20 Sep 2020 01:56:30
User entered 'Yes (Y)'	System	20 Sep 2020 01:56:30

FDA-CBER-2022-1614-0508711

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(9)
Generated On: 09 Jun 2021 15:08:42
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-19T18:56:06', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'fa2a02ec-8b83-417e-9338-61cb7c8b75aa'	System	20 Sep 2020 01:56:30
User entered '98.1'	System	20 Sep 2020 01:56:30

FDA-CBER-2022-1614-0508712

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(9)
Generated On: 09 Jun 2021 15:08:42
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-19T18:56:10', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'fa2a02ec-8b83-417e-9338-61cb7c8b75aa'	System	20 Sep 2020 01:56:30
User entered 'Yes (Y)'	System	20 Sep 2020 01:56:30

FDA-CBER-2022-1614-0508713

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(9)
Generated On: 09 Jun 2021 15:08:42
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	29 Sep 2020 19:33:03
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	Karen Mylerberg (b) (4) (b) (4)	25 Sep 2020 20:01:16
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	20 Sep 2020 01:56:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-19T18:56:17', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'fa2a02ec-8b83-417e-9338-61cb7c8b75aa'	System	20 Sep 2020 01:56:30
User entered '1'	System	20 Sep 2020 01:56:30

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(9)
Generated On: 09 Jun 2021 15:08:42
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-19T18:56:17', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'fa2a02ec-8b83-417e-9338-61cb7c8b75aa'	System	20 Sep 2020 01:56:30
User entered '0'	System	20 Sep 2020 01:56:30

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(9)
Generated On: 09 Jun 2021 15:08:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-19T18:56:27', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'fa2a02ec-8b83-417e-9338-61cb7c8b75aa'	System	20 Sep 2020 01:56:30
User entered '19 Sep 2020 18:56'	System	20 Sep 2020 01:56:30

FDA-CBER-2022-1614-0508716

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(9)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '19 Sep 2020 12:00'	System	19 Sep 2020 07:58:02

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(9)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '20 Sep 2020 11:59'	System	19 Sep 2020 07:58:02

FDA-CBER-2022-1614-0508718

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(10)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	19 Sep 2020 07:59:37
User entered 'Day 10'	System	19 Sep 2020 07:59:37

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(10)
Generated On: 09 Jun 2021 15:08:42
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-20T21:37:26', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'e285b999-f91d-40f7-be09-3dbc83dc8708'	System	21 Sep 2020 04:39:51
User entered 'Yes (Y)'	System	21 Sep 2020 04:39:51

FDA-CBER-2022-1614-0508720

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(10)
Generated On: 09 Jun 2021 15:08:42
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-20T21:37:36', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'e285b999-f91d-40f7-be09-3dbc83dc8708'	System	21 Sep 2020 04:39:51
User entered '98.3'	System	21 Sep 2020 04:39:51

FDA-CBER-2022-1614-0508721

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(10)
Generated On: 09 Jun 2021 15:08:42
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-20T21:37:46', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'e285b999-f91d-40f7-be09-3dbc83dc8708'	System	21 Sep 2020 04:39:51
User entered 'Yes (Y)'	System	21 Sep 2020 04:39:51

FDA-CBER-2022-1614-0508722

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(10)
Generated On: 09 Jun 2021 15:08:42
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	29 Sep 2020 19:33:09
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	Karen Mylerberg (b) (4) (b) (4)	25 Sep 2020 20:01:31
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	21 Sep 2020 04:39:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-20T21:37:54', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'e285b999-f91d-40f7-be09-3dbc83dc8708'	System	21 Sep 2020 04:39:51
User entered '1'	System	21 Sep 2020 04:39:51

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(10)
Generated On: 09 Jun 2021 15:08:42
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-20T21:37:54', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'e285b999-f91d-40f7-be09-3dbc83dc8708'	System	21 Sep 2020 04:39:51
User entered '0'	System	21 Sep 2020 04:39:51

FDA-CBER-2022-1614-0508724

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(10)
Generated On: 09 Jun 2021 15:08:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-20T21:39:46', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'e285b999-f91d-40f7-be09-3dbc83dc8708'	System	21 Sep 2020 04:39:51
User entered '20 Sep 2020 21:39'	System	21 Sep 2020 04:39:51

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(10)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '20 Sep 2020 12:00'	System	19 Sep 2020 07:59:37

FDA-CBER-2022-1614-0508726

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(10)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '21 Sep 2020 11:59'	System	19 Sep 2020 07:59:37

FDA-CBER-2022-1614-0508727

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(11)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	20 Sep 2020 01:56:30
User entered 'Day 11'	System	20 Sep 2020 01:56:30

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(11)
Generated On: 09 Jun 2021 15:08:42
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0508729

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(11)
Generated On: 09 Jun 2021 15:08:42
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0508730

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(11)
Generated On: 09 Jun 2021 15:08:42
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(11)
Generated On: 09 Jun 2021 15:08:42
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0508732

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(11)
Generated On: 09 Jun 2021 15:08:42
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0508733

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(11)
Generated On: 09 Jun 2021 15:08:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0508734

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(11)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '21 Sep 2020 12:00'	System	20 Sep 2020 01:56:30

FDA-CBER-2022-1614-0508735

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(11)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '22 Sep 2020 11:59'	System	20 Sep 2020 01:56:30

FDA-CBER-2022-1614-0508736

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(12)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	21 Sep 2020 04:39:51
User entered 'Day 12'	System	21 Sep 2020 04:39:51

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(12)
Generated On: 09 Jun 2021 15:08:42
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-23T09:11:04', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'c1a9e330-50b6-4cf9-abff-d7cca41a00d9'	System	23 Sep 2020 16:12:07
User entered 'Yes (Y)'	System	23 Sep 2020 16:12:07

FDA-CBER-2022-1614-0508738

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(12)
Generated On: 09 Jun 2021 15:08:42
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-23T09:11:18', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'c1a9e330-50b6-4cf9-abff-d7cca41a00d9'	System	23 Sep 2020 16:12:07
User entered '97.6'	System	23 Sep 2020 16:12:07

FDA-CBER-2022-1614-0508739

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(12)
Generated On: 09 Jun 2021 15:08:42
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-23T09:11:50', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'c1a9e330-50b6-4cf9-abff-d7cca41a00d9'	System	23 Sep 2020 16:12:07
User entered 'Yes (Y)'	System	23 Sep 2020 16:12:07

FDA-CBER-2022-1614-0508740

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(12)
Generated On: 09 Jun 2021 15:08:42
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	29 Sep 2020 19:33:19
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	Karen Mylerberg (b) (4) (b) (4)	25 Sep 2020 20:01:48
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	23 Sep 2020 16:12:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-23T09:11:54', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'c1a9e330-50b6-4cf9-abff-d7cca41a00d9'	System	23 Sep 2020 16:12:07
User entered '1'	System	23 Sep 2020 16:12:07

FDA-CBER-2022-1614-0508741

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(12)
Generated On: 09 Jun 2021 15:08:42
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-23T09:11:54', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'c1a9e330-50b6-4cf9-abff-d7cca41a00d9'	System	23 Sep 2020 16:12:07
User entered '0'	System	23 Sep 2020 16:12:07

FDA-CBER-2022-1614-0508742

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(12)
Generated On: 09 Jun 2021 15:08:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-23T09:12:02', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'c1a9e330-50b6-4cf9-abff-d7cca41a00d9'	System	23 Sep 2020 16:12:07
User entered '23 Sep 2020 09:12'	System	23 Sep 2020 16:12:07

FDA-CBER-2022-1614-0508743

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(12)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 04:39:51

FDA-CBER-2022-1614-0508744

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(12)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 04:39:51

FDA-CBER-2022-1614-0508745

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(13)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	23 Sep 2020 16:12:07
User entered 'Day 13'	System	23 Sep 2020 16:12:07

FDA-CBER-2022-1614-0508746

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(13)
Generated On: 09 Jun 2021 15:08:42
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0508747

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(13)
Generated On: 09 Jun 2021 15:08:42
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0508748

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(13)
Generated On: 09 Jun 2021 15:08:42
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0508749

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(13)
Generated On: 09 Jun 2021 15:08:42
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0508750

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(13)
Generated On: 09 Jun 2021 15:08:42
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0508751

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(13)
Generated On: 09 Jun 2021 15:08:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0508752

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(13)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '23 Sep 2020 12:00'	System	23 Sep 2020 16:12:07

FDA-CBER-2022-1614-0508753

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(13)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 16:12:07

FDA-CBER-2022-1614-0508754

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(14)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	23 Sep 2020 16:12:07
User entered 'Day 14'	System	23 Sep 2020 16:12:07

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(14)
Generated On: 09 Jun 2021 15:08:42
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-24T18:26:56', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '29d2c620-5529-4ff0-995b-de5fafa4430b'	System	25 Sep 2020 01:27:33
User entered 'Yes (Y)'	System	25 Sep 2020 01:27:33

FDA-CBER-2022-1614-0508756

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(14)
Generated On: 09 Jun 2021 15:08:42
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-24T18:27:05', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '29d2c620-5529-4ff0-995b-de5fafa4430b'	System	25 Sep 2020 01:27:33
User entered '98.8'	System	25 Sep 2020 01:27:33

FDA-CBER-2022-1614-0508757

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(14)
Generated On: 09 Jun 2021 15:08:42
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-24T18:27:13', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '29d2c620-5529-4ff0-995b-de5fafa4430b'	System	25 Sep 2020 01:27:33
User entered 'Yes (Y)'	System	25 Sep 2020 01:27:33

FDA-CBER-2022-1614-0508758

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(14)
Generated On: 09 Jun 2021 15:08:42
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	29 Sep 2020 19:33:30
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	Karen Mylerberg (b) (4) (b) (4)	25 Sep 2020 20:02:02
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	25 Sep 2020 01:27:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-24T18:27:18', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '29d2c620-5529-4ff0-995b-de5fafa4430b'	System	25 Sep 2020 01:27:33
User entered '1'	System	25 Sep 2020 01:27:33

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(14)
Generated On: 09 Jun 2021 15:08:42
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-24T18:27:18', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '29d2c620-5529-4ff0-995b-de5fafa4430b'	System	25 Sep 2020 01:27:33
User entered '0'	System	25 Sep 2020 01:27:33

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(14)
Generated On: 09 Jun 2021 15:08:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-24T18:27:25', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '29d2c620-5529-4ff0-995b-de5fafa4430b'	System	25 Sep 2020 01:27:33
User entered '24 Sep 2020 18:27'	System	25 Sep 2020 01:27:33

FDA-CBER-2022-1614-0508761

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(14)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 16:12:07

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(14)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 16:12:07

FDA-CBER-2022-1614-0508763

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(15)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	25 Sep 2020 01:27:33
User entered 'Day 15'	System	25 Sep 2020 01:27:33

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(15)
Generated On: 09 Jun 2021 15:08:42
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-25T22:27:21', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '8fd2e467-62ad-4086-8672-3c74f85c1d32'	System	26 Sep 2020 05:27:58
User entered 'Yes (Y)'	System	26 Sep 2020 05:27:58

FDA-CBER-2022-1614-0508765

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(15)
Generated On: 09 Jun 2021 15:08:42
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-25T22:27:35', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '8fd2e467-62ad-4086-8672-3c74f85c1d32'	System	26 Sep 2020 05:27:58
User entered '98.8'	System	26 Sep 2020 05:27:58

FDA-CBER-2022-1614-0508766

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(15)
Generated On: 09 Jun 2021 15:08:42
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-25T22:27:43', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '8fd2e467-62ad-4086-8672-3c74f85c1d32'	System	26 Sep 2020 05:27:58
User entered 'Yes (Y)'	System	26 Sep 2020 05:27:58

FDA-CBER-2022-1614-0508767

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(15)
Generated On: 09 Jun 2021 15:08:42
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	19 Oct 2020 02:36:58
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'updated' (Site from System).	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 16:55:20
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	26 Sep 2020 05:27:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-25T22:27:48', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '8fd2e467-62ad-4086-8672-3c74f85c1d32'	System	26 Sep 2020 05:27:58
User entered '1'	System	26 Sep 2020 05:27:58

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(15)
Generated On: 09 Jun 2021 15:08:42
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-25T22:27:48', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '8fd2e467-62ad-4086-8672-3c74f85c1d32'	System	26 Sep 2020 05:27:58
User entered '0'	System	26 Sep 2020 05:27:58

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(15)
Generated On: 09 Jun 2021 15:08:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-25T22:27:55', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '8fd2e467-62ad-4086-8672-3c74f85c1d32'	System	26 Sep 2020 05:27:58
User entered '25 Sep 2020 22:27'	System	26 Sep 2020 05:27:58

FDA-CBER-2022-1614-0508770

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(15)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '25 Sep 2020 12:00'	System	25 Sep 2020 01:27:33

FDA-CBER-2022-1614-0508771

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(15)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '26 Sep 2020 11:59'	System	25 Sep 2020 01:27:33

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(16)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	25 Sep 2020 01:27:33
User entered 'Day 16'	System	25 Sep 2020 01:27:33

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(16)
Generated On: 09 Jun 2021 15:08:42
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-26T18:15:17', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '3f621fd1-8cf2-400a-b638-14ce1f6c16c9'	System	27 Sep 2020 01:15:56
User entered 'Yes (Y)'	System	27 Sep 2020 01:15:56

FDA-CBER-2022-1614-0508774

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(16)
Generated On: 09 Jun 2021 15:08:42
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-26T18:15:31', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '3f621fd1-8cf2-400a-b638-14ce1f6c16c9'	System	27 Sep 2020 01:15:56
User entered '99.0'	System	27 Sep 2020 01:15:56

FDA-CBER-2022-1614-0508775

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(16)
Generated On: 09 Jun 2021 15:08:42
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-26T18:15:37', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '3f621fd1-8cf2-400a-b638-14ce1f6c16c9'	System	27 Sep 2020 01:15:56
User entered 'Yes (Y)'	System	27 Sep 2020 01:15:56

FDA-CBER-2022-1614-0508776

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(16)
Generated On: 09 Jun 2021 15:08:42
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	19 Oct 2020 02:39:31
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'updated' (Site from System).	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 16:55:32
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	27 Sep 2020 01:15:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-26T18:15:42', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '3f621fd1-8cf2-400a-b638-14ce1f6c16c9'	System	27 Sep 2020 01:15:56
User entered '1'	System	27 Sep 2020 01:15:56

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(16)
Generated On: 09 Jun 2021 15:08:42
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-26T18:15:42', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '3f621fd1-8cf2-400a-b638-14ce1f6c16c9'	System	27 Sep 2020 01:15:56
User entered '0'	System	27 Sep 2020 01:15:56

FDA-CBER-2022-1614-0508778

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(16)
Generated On: 09 Jun 2021 15:08:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-26T18:15:49', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '3f621fd1-8cf2-400a-b638-14ce1f6c16c9'	System	27 Sep 2020 01:15:56
User entered '26 Sep 2020 18:15'	System	27 Sep 2020 01:15:56

FDA-CBER-2022-1614-0508779

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(16)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 01:27:33

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(16)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 01:27:33

FDA-CBER-2022-1614-0508781

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(17)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	26 Sep 2020 05:27:58
User entered 'Day 17'	System	26 Sep 2020 05:27:58

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(17)
Generated On: 09 Jun 2021 15:08:42
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-27T13:27:16', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '0f69ea47-137e-4c6f-829d-3470f66607ac'	System	27 Sep 2020 20:27:53
User entered 'Yes (Y)'	System	27 Sep 2020 20:27:53

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(17)
Generated On: 09 Jun 2021 15:08:42
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-27T13:27:33', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '0f69ea47-137e-4c6f-829d-3470f66607ac'	System	27 Sep 2020 20:27:53
User entered '98.5'	System	27 Sep 2020 20:27:53

FDA-CBER-2022-1614-0508784

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(17)
Generated On: 09 Jun 2021 15:08:42
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-27T13:27:38', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '0f69ea47-137e-4c6f-829d-3470f66607ac'	System	27 Sep 2020 20:27:53
User entered 'No (N)'	System	27 Sep 2020 20:27:53

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(17)
Generated On: 09 Jun 2021 15:08:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-27T13:27:49', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '0f69ea47-137e-4c6f-829d-3470f66607ac'	System	27 Sep 2020 20:27:53
User entered '27 Sep 2020 13:27'	System	27 Sep 2020 20:27:53

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(17)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '27 Sep 2020 12:00'	System	26 Sep 2020 05:27:58

FDA-CBER-2022-1614-0508787

US3112192
Folder: Diary Dose 2 (1)
Form: Temperature_Day(17)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '28 Sep 2020 11:59'	System	26 Sep 2020 05:27:58

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	11 Sep 2020 18:03:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 18:03:18

FDA-CBER-2022-1614-0508789

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:08:42
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-11T11:34:56', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'ac4f4078-3a3f-4fd7-a532-436ade117012'	System	11 Sep 2020 18:35:22
User entered 'None (1)'	System	11 Sep 2020 18:35:22

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:08:42
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-11T11:35:00', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'ac4f4078-3a3f-4fd7-a532-436ade117012'	System	11 Sep 2020 18:35:22
User entered 'No (N)'	System	11 Sep 2020 18:35:22

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:08:42
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-11T11:35:04', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'ac4f4078-3a3f-4fd7-a532-436ade117012'	System	11 Sep 2020 18:35:22
User entered 'No (N)'	System	11 Sep 2020 18:35:22

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:08:42
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-11T11:35:08', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'ac4f4078-3a3f-4fd7-a532-436ade117012'	System	11 Sep 2020 18:35:22
User entered 'None (1)'	System	11 Sep 2020 18:35:22

FDA-CBER-2022-1614-0508793

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:08:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-11T11:35:18', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'ac4f4078-3a3f-4fd7-a532-436ade117012'	System	11 Sep 2020 18:35:22
User entered '11 Sep 2020 11:35'	System	11 Sep 2020 18:35:22

FDA-CBER-2022-1614-0508794

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '11 Sep 2020 11:04'	System	11 Sep 2020 18:03:18

FDA-CBER-2022-1614-0508795

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '11 Sep 2020 13:34'	System	11 Sep 2020 18:03:18

FDA-CBER-2022-1614-0508796

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	11 Sep 2020 18:03:18
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 18:03:18

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:08:42
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0508798

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:08:42
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0508799

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:08:42
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)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0508800

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:08:42
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0508801

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:08:42
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)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0508802

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:08:42
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0508803

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:08:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0508804

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '11 Sep 2020 14:29'	System	11 Sep 2020 18:03:18

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 18:03:18

FDA-CBER-2022-1614-0508806

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	11 Sep 2020 18:03:18
User entered 'Day 2'	System	11 Sep 2020 18:03:18

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:08:42
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-12T21:50:58', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '6499dfac-5b80-4765-9fa9-8e34b3c3e8d2'	System	13 Sep 2020 04:51:42
User entered 'None (1)'	System	13 Sep 2020 04:51:42

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:08:42
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-12T21:51:03', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '6499dfac-5b80-4765-9fa9-8e34b3c3e8d2'	System	13 Sep 2020 04:51:42
User entered 'No (N)'	System	13 Sep 2020 04:51:42

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:08:42
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-12T21:51:10', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '6499dfac-5b80-4765-9fa9-8e34b3c3e8d2'	System	13 Sep 2020 04:51:42
User entered 'No (N)'	System	13 Sep 2020 04:51:42

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:08:42
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-12T21:51:25', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '6499dfac-5b80-4765-9fa9-8e34b3c3e8d2'	System	13 Sep 2020 04:51:42
User entered 'Does not interfere with activity (2)'	System	13 Sep 2020 04:51:42

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:08:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-12T21:51:38', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '6499dfac-5b80-4765-9fa9-8e34b3c3e8d2'	System	13 Sep 2020 04:51:42
User entered '12 Sep 2020 21:51'	System	13 Sep 2020 04:51:42

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 18:03:18

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 18:03:18

FDA-CBER-2022-1614-0508814

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	11 Sep 2020 18:03:18
User entered 'Day 3'	System	11 Sep 2020 18:03:18

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:08:42
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-13T23:20:40', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '03679a54-43ea-429c-8cab-6a53fe0d9c03'	System	14 Sep 2020 06:22:08
User entered 'Does not interfere with activity (2)'	System	14 Sep 2020 06:22:08

FDA-CBER-2022-1614-0508816

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:08:42
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-13T23:20:45', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '03679a54-43ea-429c-8cab-6a53fe0d9c03'	System	14 Sep 2020 06:22:08
User entered 'Yes (Y)'	System	14 Sep 2020 06:22:08

FDA-CBER-2022-1614-0508817

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:08:42
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)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-13T23:21:51', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '03679a54-43ea-429c-8cab-6a53fe0d9c03'	System	14 Sep 2020 06:22:08
User entered '8'	System	14 Sep 2020 06:22:08

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:08:42
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-13T23:21:14', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '03679a54-43ea-429c-8cab-6a53fe0d9c03'	System	14 Sep 2020 06:22:08
User entered 'No (N)'	System	14 Sep 2020 06:22:08

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:08:42
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-13T23:21:27', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '03679a54-43ea-429c-8cab-6a53fe0d9c03'	System	14 Sep 2020 06:22:08
User entered 'Does not interfere with activity (2)'	System	14 Sep 2020 06:22:08

FDA-CBER-2022-1614-0508820

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:08:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-13T23:22:04', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '03679a54-43ea-429c-8cab-6a53fe0d9c03'	System	14 Sep 2020 06:22:08
User entered '13 Sep 2020 23:22'	System	14 Sep 2020 06:22:08

FDA-CBER-2022-1614-0508821

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 18:03:18

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 18:03:18

FDA-CBER-2022-1614-0508823

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	11 Sep 2020 18:03:18
User entered 'Day 4'	System	11 Sep 2020 18:03:18

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:08:42
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-15T08:33:04', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '281e94f5-2963-4f99-8ce4-67213b50871e'	System	15 Sep 2020 15:33:36
User entered 'None (1)'	System	15 Sep 2020 15:33:36

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:08:42
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-15T08:33:10', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '281e94f5-2963-4f99-8ce4-67213b50871e'	System	15 Sep 2020 15:33:36
User entered 'No (N)'	System	15 Sep 2020 15:33:36

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:08:42
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-15T08:33:14', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '281e94f5-2963-4f99-8ce4-67213b50871e'	System	15 Sep 2020 15:33:36
User entered 'No (N)'	System	15 Sep 2020 15:33:36

FDA-CBER-2022-1614-0508827

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:08:42
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-15T08:33:23', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '281e94f5-2963-4f99-8ce4-67213b50871e'	System	15 Sep 2020 15:33:36
User entered 'Does not interfere with activity (2)'	System	15 Sep 2020 15:33:36

FDA-CBER-2022-1614-0508828

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:08:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-15T08:33:32', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '281e94f5-2963-4f99-8ce4-67213b50871e'	System	15 Sep 2020 15:33:36
User entered '15 Sep 2020 08:33'	System	15 Sep 2020 15:33:36

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 18:03:18

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 18:03:18

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	11 Sep 2020 18:03:18
User entered 'Day 5'	System	11 Sep 2020 18:03:18

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:08:42
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-15T13:44:04', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '682e5a0c-8cbc-4b56-bfa8-19c8f3573bfd'	System	15 Sep 2020 20:44:58
User entered 'None (1)'	System	15 Sep 2020 20:44:58

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:08:42
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-15T13:44:11', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '682e5a0c-8cbc-4b56-bfa8-19c8f3573bfd'	System	15 Sep 2020 20:44:58
User entered 'No (N)'	System	15 Sep 2020 20:44:58

FDA-CBER-2022-1614-0508834

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:08:42
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-15T13:44:29', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '682e5a0c-8cbc-4b56-bfa8-19c8f3573bfd'	System	15 Sep 2020 20:44:58
User entered 'No (N)'	System	15 Sep 2020 20:44:58

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:08:42
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-15T13:44:42', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '682e5a0c-8cbc-4b56-bfa8-19c8f3573bfd'	System	15 Sep 2020 20:44:58
User entered 'None (1)'	System	15 Sep 2020 20:44:58

FDA-CBER-2022-1614-0508836

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:08:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-15T13:44:53', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '682e5a0c-8cbc-4b56-bfa8-19c8f3573bfd'	System	15 Sep 2020 20:44:58
User entered '15 Sep 2020 13:44'	System	15 Sep 2020 20:44:58

FDA-CBER-2022-1614-0508837

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 18:03:18

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 18:03:18

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	11 Sep 2020 18:03:18
User entered 'Day 6'	System	11 Sep 2020 18:03:18

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:08:42
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-16T15:27:12', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '6dc41b9a-aae0-4162-b489-861cf2725e48'	System	16 Sep 2020 22:27:36
User entered 'None (1)'	System	16 Sep 2020 22:27:36

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:08:42
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-16T15:27:16', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '6dc41b9a-aae0-4162-b489-861cf2725e48'	System	16 Sep 2020 22:27:36
User entered 'No (N)'	System	16 Sep 2020 22:27:36

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:08:42
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-16T15:27:20', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '6dc41b9a-aae0-4162-b489-861cf2725e48'	System	16 Sep 2020 22:27:36
User entered 'No (N)'	System	16 Sep 2020 22:27:36

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:08:42
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-16T15:27:25', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '6dc41b9a-aae0-4162-b489-861cf2725e48'	System	16 Sep 2020 22:27:36
User entered 'None (1)'	System	16 Sep 2020 22:27:36

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:08:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-16T15:27:31', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '6dc41b9a-aae0-4162-b489-861cf2725e48'	System	16 Sep 2020 22:27:36
User entered '16 Sep 2020 15:27'	System	16 Sep 2020 22:27:36

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 18:03:18

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 18:03:18

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	11 Sep 2020 18:03:18
User entered 'Day 7'	System	11 Sep 2020 18:03:18

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:08:42
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-17T12:53:05', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '71e83d32-9f51-43fd-9281-733929640359'	System	19 Sep 2020 07:58:10
User entered 'None (1)'	System	19 Sep 2020 07:58:10

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:08:42
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-17T12:53:09', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '71e83d32-9f51-43fd-9281-733929640359'	System	19 Sep 2020 07:58:10
User entered 'No (N)'	System	19 Sep 2020 07:58:10

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:08:42
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-17T12:53:13', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '71e83d32-9f51-43fd-9281-733929640359'	System	19 Sep 2020 07:58:10
User entered 'No (N)'	System	19 Sep 2020 07:58:10

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:08:42
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-17T12:53:19', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '71e83d32-9f51-43fd-9281-733929640359'	System	19 Sep 2020 07:58:10
User entered 'Does not interfere with activity (2)'	System	19 Sep 2020 07:58:10

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:08:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-17T12:53:24', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '71e83d32-9f51-43fd-9281-733929640359'	System	19 Sep 2020 07:58:10
User entered '17 Sep 2020 12:53'	System	19 Sep 2020 07:58:10

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 18:03:18

US3112192
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 18:03:18

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	11 Sep 2020 18:03:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 18:03:18

FDA-CBER-2022-1614-0508856

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:08:42
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-11T11:35:27', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'eacb67a4-a9ad-4f24-a481-d72d9891fcb1'	System	11 Sep 2020 18:36:03
User entered 'None (0)'	System	11 Sep 2020 18:36:03

FDA-CBER-2022-1614-0508857

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:08:42
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-11T11:35:33', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'eacb67a4-a9ad-4f24-a481-d72d9891fcb1'	System	11 Sep 2020 18:36:03
User entered 'No interference with activity (1)'	System	11 Sep 2020 18:36:03

FDA-CBER-2022-1614-0508858

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:08:42
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-11T11:35:37', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'eacb67a4-a9ad-4f24-a481-d72d9891fcb1'	System	11 Sep 2020 18:36:03
User entered 'No interference with activity (1)'	System	11 Sep 2020 18:36:03

FDA-CBER-2022-1614-0508859

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:08:42
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-11T11:35:41', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'eacb67a4-a9ad-4f24-a481-d72d9891fcb1'	System	11 Sep 2020 18:36:03
User entered 'No interference with activity (1)'	System	11 Sep 2020 18:36:03

FDA-CBER-2022-1614-0508860

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:08:42
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-11T11:35:44', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'eacb67a4-a9ad-4f24-a481-d72d9891fcb1'	System	11 Sep 2020 18:36:03
User entered 'None (0)'	System	11 Sep 2020 18:36:03

FDA-CBER-2022-1614-0508861

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:08:42
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-11T11:35:47', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'eacb67a4-a9ad-4f24-a481-d72d9891fcb1'	System	11 Sep 2020 18:36:03
User entered 'None (0)'	System	11 Sep 2020 18:36:03

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:08:42
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-11T11:35:56', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'eacb67a4-a9ad-4f24-a481-d72d9891fcb1'	System	11 Sep 2020 18:36:03
User entered 'No (N)'	System	11 Sep 2020 18:36:03

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-11T11:36:00', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'eacb67a4-a9ad-4f24-a481-d72d9891fcb1'	System	11 Sep 2020 18:36:03
User entered '11 Sep 2020 11:36'	System	11 Sep 2020 18:36:03

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '11 Sep 2020 11:04'	System	11 Sep 2020 18:03:18

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '11 Sep 2020 13:34'	System	11 Sep 2020 18:03:18

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	11 Sep 2020 18:03:18
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 18:03:18

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:08:42
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0508868

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:08:42
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0508869

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:08:42
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0508870

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:08:42
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0508871

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:08:42
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0508872

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:08:42
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0508873

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:08:42
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0508875

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '11 Sep 2020 14:29'	System	11 Sep 2020 18:03:18

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 18:03:18

FDA-CBER-2022-1614-0508877

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	11 Sep 2020 18:03:18
User entered 'Day 2'	System	11 Sep 2020 18:03:18

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:08:42
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-12T21:51:52', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'caebb42a-d4c3-475e-828f-4121d1f39046'	System	13 Sep 2020 04:52:42
User entered 'No interference with activity (1)'	System	13 Sep 2020 04:52:42

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:08:42
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-12T21:52:00', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'caebb42a-d4c3-475e-828f-4121d1f39046'	System	13 Sep 2020 04:52:42
User entered 'No interference with activity (1)'	System	13 Sep 2020 04:52:42

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:08:42
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-12T21:52:05', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'caebb42a-d4c3-475e-828f-4121d1f39046'	System	13 Sep 2020 04:52:42
User entered 'Some interference with activity (2)'	System	13 Sep 2020 04:52:42

FDA-CBER-2022-1614-0508881

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:08:42
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-12T21:52:12', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'caebb42a-d4c3-475e-828f-4121d1f39046'	System	13 Sep 2020 04:52:42
User entered 'No interference with activity (1)'	System	13 Sep 2020 04:52:42

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:08:42
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-12T21:52:18', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'caebb42a-d4c3-475e-828f-4121d1f39046'	System	13 Sep 2020 04:52:42
User entered 'None (0)'	System	13 Sep 2020 04:52:42

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:08:42
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-12T21:52:21', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'caebb42a-d4c3-475e-828f-4121d1f39046'	System	13 Sep 2020 04:52:42
User entered 'None (0)'	System	13 Sep 2020 04:52:42

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:08:42
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-12T21:52:27', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'caebb42a-d4c3-475e-828f-4121d1f39046'	System	13 Sep 2020 04:52:42
User entered 'No (N)'	System	13 Sep 2020 04:52:42

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-12T21:52:37', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'caebb42a-d4c3-475e-828f-4121d1f39046'	System	13 Sep 2020 04:52:42
User entered '12 Sep 2020 21:52'	System	13 Sep 2020 04:52:42

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 18:03:18

FDA-CBER-2022-1614-0508887

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 18:03:18

FDA-CBER-2022-1614-0508888

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	11 Sep 2020 18:03:18
User entered 'Day 3'	System	11 Sep 2020 18:03:18

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:08:42
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-13T23:22:14', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'e60d992e-2d86-4bf9-9d12-c4a1ae0e70ea'	System	14 Sep 2020 06:23:26
User entered 'No interference with activity (1)'	System	14 Sep 2020 06:23:26

FDA-CBER-2022-1614-0508890

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:08:42
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-13T23:22:21', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'e60d992e-2d86-4bf9-9d12-c4a1ae0e70ea'	System	14 Sep 2020 06:23:26
User entered 'Some interference with activity (2)'	System	14 Sep 2020 06:23:26

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:08:42
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-13T23:22:31', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'e60d992e-2d86-4bf9-9d12-c4a1ae0e70ea'	System	14 Sep 2020 06:23:26
User entered 'Some interference with activity (2)'	System	14 Sep 2020 06:23:26

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:08:42
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-13T23:22:39', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'e60d992e-2d86-4bf9-9d12-c4a1ae0e70ea'	System	14 Sep 2020 06:23:26
User entered 'Some interference with activity (2)'	System	14 Sep 2020 06:23:26

FDA-CBER-2022-1614-0508893

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:08:42
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-13T23:22:50', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'e60d992e-2d86-4bf9-9d12-c4a1ae0e70ea'	System	14 Sep 2020 06:23:26
User entered 'None (0)'	System	14 Sep 2020 06:23:26

FDA-CBER-2022-1614-0508894

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:08:42
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-13T23:22:57', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'e60d992e-2d86-4bf9-9d12-c4a1ae0e70ea'	System	14 Sep 2020 06:23:26
User entered 'No interference with activity (1)'	System	14 Sep 2020 06:23:26

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:08:42
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-13T23:23:03', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'e60d992e-2d86-4bf9-9d12-c4a1ae0e70ea'	System	14 Sep 2020 06:23:26
User entered 'No (N)'	System	14 Sep 2020 06:23:26

FDA-CBER-2022-1614-0508896

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-13T23:23:23', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'e60d992e-2d86-4bf9-9d12-c4a1ae0e70ea'	System	14 Sep 2020 06:23:26
User entered '13 Sep 2020 23:23'	System	14 Sep 2020 06:23:26

FDA-CBER-2022-1614-0508897

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 18:03:18

FDA-CBER-2022-1614-0508898

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 18:03:18

FDA-CBER-2022-1614-0508899

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	11 Sep 2020 18:03:18
User entered 'Day 4'	System	11 Sep 2020 18:03:18

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:08:42
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-15T08:33:46', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '3d168287-dc6f-4f09-8af5-76442fd811c2'	System	15 Sep 2020 15:34:46
User entered 'No interference with activity (1)'	System	15 Sep 2020 15:34:46

FDA-CBER-2022-1614-0508901

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:08:42
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-15T08:33:52', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '3d168287-dc6f-4f09-8af5-76442fd811c2'	System	15 Sep 2020 15:34:46
User entered 'Some interference with activity (2)'	System	15 Sep 2020 15:34:46

FDA-CBER-2022-1614-0508902

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:08:42
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-15T08:34:00', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '3d168287-dc6f-4f09-8af5-76442fd811c2'	System	15 Sep 2020 15:34:46
User entered 'Some interference with activity (2)'	System	15 Sep 2020 15:34:46

FDA-CBER-2022-1614-0508903

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:08:42
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-15T08:34:11', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '3d168287-dc6f-4f09-8af5-76442fd811c2'	System	15 Sep 2020 15:34:46
User entered 'Some interference with activity (2)'	System	15 Sep 2020 15:34:46

FDA-CBER-2022-1614-0508904

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:08:42
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-15T08:34:22', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '3d168287-dc6f-4f09-8af5-76442fd811c2'	System	15 Sep 2020 15:34:46
User entered 'None (0)'	System	15 Sep 2020 15:34:46

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:08:42
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-15T08:34:25', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '3d168287-dc6f-4f09-8af5-76442fd811c2'	System	15 Sep 2020 15:34:46
User entered 'None (0)'	System	15 Sep 2020 15:34:46

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:08:42
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-15T08:34:31', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '3d168287-dc6f-4f09-8af5-76442fd811c2'	System	15 Sep 2020 15:34:46
User entered 'No (N)'	System	15 Sep 2020 15:34:46

FDA-CBER-2022-1614-0508907

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-15T08:34:43', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '3d168287-dc6f-4f09-8af5-76442fd811c2'	System	15 Sep 2020 15:34:46
User entered '15 Sep 2020 08:34'	System	15 Sep 2020 15:34:46

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 18:03:18

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 18:03:18

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	11 Sep 2020 18:03:18
User entered 'Day 5'	System	11 Sep 2020 18:03:18

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:08:42
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-15T13:42:52', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '001866cf-5768-4a23-a033-e613c7bd24b7'	System	15 Sep 2020 20:43:54
User entered 'None (0)'	System	15 Sep 2020 20:43:54

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:08:42
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-15T13:43:00', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '001866cf-5768-4a23-a033-e613c7bd24b7'	System	15 Sep 2020 20:43:54
User entered 'Some interference with activity (2)'	System	15 Sep 2020 20:43:54

FDA-CBER-2022-1614-0508913

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:08:42
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-15T13:43:06', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '001866cf-5768-4a23-a033-e613c7bd24b7'	System	15 Sep 2020 20:43:54
User entered 'Some interference with activity (2)'	System	15 Sep 2020 20:43:54

FDA-CBER-2022-1614-0508914

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:08:42
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-15T13:43:17', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '001866cf-5768-4a23-a033-e613c7bd24b7'	System	15 Sep 2020 20:43:54
User entered 'Some interference with activity (2)'	System	15 Sep 2020 20:43:54

FDA-CBER-2022-1614-0508915

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:08:42
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-15T13:43:25', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '001866cf-5768-4a23-a033-e613c7bd24b7'	System	15 Sep 2020 20:43:54
User entered 'None (0)'	System	15 Sep 2020 20:43:54

FDA-CBER-2022-1614-0508916

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:08:42
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-15T13:43:29', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '001866cf-5768-4a23-a033-e613c7bd24b7'	System	15 Sep 2020 20:43:54
User entered 'None (0)'	System	15 Sep 2020 20:43:54

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:08:42
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-15T13:43:35', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '001866cf-5768-4a23-a033-e613c7bd24b7'	System	15 Sep 2020 20:43:54
User entered 'No (N)'	System	15 Sep 2020 20:43:54

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-15T13:43:50', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '001866cf-5768-4a23-a033-e613c7bd24b7'	System	15 Sep 2020 20:43:54
User entered '15 Sep 2020 13:43'	System	15 Sep 2020 20:43:54

FDA-CBER-2022-1614-0508919

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 18:03:18

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 18:03:18

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	11 Sep 2020 18:03:18
User entered 'Day 6'	System	11 Sep 2020 18:03:18

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:08:42
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-16T15:26:00', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '4ea06bd6-2972-475d-a93e-22012cbeea3c'	System	16 Sep 2020 22:27:01
User entered 'None (0)'	System	16 Sep 2020 22:27:01

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:08:42
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-16T15:26:06', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '4ea06bd6-2972-475d-a93e-22012cbeea3c'	System	16 Sep 2020 22:27:01
User entered 'Some interference with activity (2)'	System	16 Sep 2020 22:27:01

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:08:42
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-16T15:26:18', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '4ea06bd6-2972-475d-a93e-22012cbeea3c'	System	16 Sep 2020 22:27:01
User entered 'Some interference with activity (2)'	System	16 Sep 2020 22:27:01

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:08:42
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-16T15:26:27', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '4ea06bd6-2972-475d-a93e-22012cbeea3c'	System	16 Sep 2020 22:27:01
User entered 'No interference with activity (1)'	System	16 Sep 2020 22:27:01

FDA-CBER-2022-1614-0508926

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:08:42
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-16T15:26:31', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '4ea06bd6-2972-475d-a93e-22012cbeea3c'	System	16 Sep 2020 22:27:01
User entered 'None (0)'	System	16 Sep 2020 22:27:01

FDA-CBER-2022-1614-0508927

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:08:42
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-16T15:26:34', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '4ea06bd6-2972-475d-a93e-22012cbeea3c'	System	16 Sep 2020 22:27:01
User entered 'None (0)'	System	16 Sep 2020 22:27:01

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:08:42
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-16T15:26:46', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '4ea06bd6-2972-475d-a93e-22012cbeea3c'	System	16 Sep 2020 22:27:01
User entered 'No (N)'	System	16 Sep 2020 22:27:01

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-16T15:26:57', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '4ea06bd6-2972-475d-a93e-22012cbeea3c'	System	16 Sep 2020 22:27:01
User entered '16 Sep 2020 15:26'	System	16 Sep 2020 22:27:01

FDA-CBER-2022-1614-0508930

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 18:03:18

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 18:03:18

FDA-CBER-2022-1614-0508932

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	11 Sep 2020 18:03:18
User entered 'Day 7'	System	11 Sep 2020 18:03:18

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:08:42
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-17T12:53:29', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '3299bf87-9fa5-489f-a5f5-67eb42f8d7a1'	System	19 Sep 2020 07:58:02
User entered 'None (0)'	System	19 Sep 2020 07:58:02

FDA-CBER-2022-1614-0508934

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:08:42
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-17T12:53:33', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '3299bf87-9fa5-489f-a5f5-67eb42f8d7a1'	System	19 Sep 2020 07:58:02
User entered 'Some interference with activity (2)'	System	19 Sep 2020 07:58:02

FDA-CBER-2022-1614-0508935

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:08:42
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-17T12:53:37', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '3299bf87-9fa5-489f-a5f5-67eb42f8d7a1'	System	19 Sep 2020 07:58:02
User entered 'Some interference with activity (2)'	System	19 Sep 2020 07:58:02

FDA-CBER-2022-1614-0508936

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:08:42
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-17T12:53:41', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '3299bf87-9fa5-489f-a5f5-67eb42f8d7a1'	System	19 Sep 2020 07:58:02
User entered 'Some interference with activity (2)'	System	19 Sep 2020 07:58:02

FDA-CBER-2022-1614-0508937

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:08:42
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-17T12:53:45', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '3299bf87-9fa5-489f-a5f5-67eb42f8d7a1'	System	19 Sep 2020 07:58:02
User entered 'None (0)'	System	19 Sep 2020 07:58:02

FDA-CBER-2022-1614-0508938

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:08:42
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-17T12:53:49', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '3299bf87-9fa5-489f-a5f5-67eb42f8d7a1'	System	19 Sep 2020 07:58:02
User entered 'None (0)'	System	19 Sep 2020 07:58:02

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:08:42
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-17T12:53:56', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '3299bf87-9fa5-489f-a5f5-67eb42f8d7a1'	System	19 Sep 2020 07:58:02
User entered 'No (N)'	System	19 Sep 2020 07:58:02

FDA-CBER-2022-1614-0508940

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-17T12:54:01', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '3299bf87-9fa5-489f-a5f5-67eb42f8d7a1'	System	19 Sep 2020 07:58:02
User entered '17 Sep 2020 12:54'	System	19 Sep 2020 07:58:02

FDA-CBER-2022-1614-0508941

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 18:03:18

US3112192
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 18:03:18

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(8)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	16 Sep 2020 22:27:01
User entered 'Day 8'	System	16 Sep 2020 22:27:01

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(8)
Generated On: 09 Jun 2021 15:08:42
Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-19T00:59:44', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'c2e20cb1-915e-4101-a42e-75d58555f3ab'	System	19 Sep 2020 07:59:53
User entered 'No interference with activity (1)'	System	19 Sep 2020 07:59:53

FDA-CBER-2022-1614-0508945

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(8)
Generated On: 09 Jun 2021 15:08:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-19T00:59:50', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'c2e20cb1-915e-4101-a42e-75d58555f3ab'	System	19 Sep 2020 07:59:53
User entered '19 Sep 2020 00:59'	System	19 Sep 2020 07:59:53

FDA-CBER-2022-1614-0508946

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(8)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 22:27:01

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(8)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 22:27:01

FDA-CBER-2022-1614-0508948

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(9)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	19 Sep 2020 07:58:02
User entered 'Day 9'	System	19 Sep 2020 07:58:02

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(9)
Generated On: 09 Jun 2021 15:08:42
Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-19T18:56:37', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '81a0c0ab-f5d4-4b0d-bcc6-b890fb26626c'	System	20 Sep 2020 01:56:50
User entered 'Some interference with activity (2)'	System	20 Sep 2020 01:56:50

FDA-CBER-2022-1614-0508950

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(9)
Generated On: 09 Jun 2021 15:08:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-19T18:56:44', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '81a0c0ab-f5d4-4b0d-bcc6-b890fb26626c'	System	20 Sep 2020 01:56:50
User entered '19 Sep 2020 18:56'	System	20 Sep 2020 01:56:50

FDA-CBER-2022-1614-0508951

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(9)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '19 Sep 2020 12:00'	System	19 Sep 2020 07:58:02

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(9)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '20 Sep 2020 11:59'	System	19 Sep 2020 07:58:02

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(10)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	19 Sep 2020 07:59:53
User entered 'Day 10'	System	19 Sep 2020 07:59:53

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(10)
Generated On: 09 Jun 2021 15:08:42
Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-20T21:43:42', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'b6087461-3b0a-4140-af33-ffcb0778dcf9'	System	21 Sep 2020 04:44:12
User entered 'No interference with activity (1)'	System	21 Sep 2020 04:44:12

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(10)
Generated On: 09 Jun 2021 15:08:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-20T21:44:10', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'b6087461-3b0a-4140-af33-ffcb0778dcf9'	System	21 Sep 2020 04:44:12
User entered '20 Sep 2020 21:44'	System	21 Sep 2020 04:44:12

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(10)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '20 Sep 2020 12:00'	System	19 Sep 2020 07:59:53

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(10)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '21 Sep 2020 11:59'	System	19 Sep 2020 07:59:53

FDA-CBER-2022-1614-0508958

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(11)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	20 Sep 2020 01:56:50
User entered 'Day 11'	System	20 Sep 2020 01:56:50

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(11)
Generated On: 09 Jun 2021 15:08:42
Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0508960

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(11)
Generated On: 09 Jun 2021 15:08:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0508961

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(11)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '21 Sep 2020 12:00'	System	20 Sep 2020 01:56:50

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(11)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '22 Sep 2020 11:59'	System	20 Sep 2020 01:56:50

FDA-CBER-2022-1614-0508963

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(12)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	21 Sep 2020 04:44:12
User entered 'Day 12'	System	21 Sep 2020 04:44:12

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(12)
Generated On: 09 Jun 2021 15:08:42
Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-23T09:12:07', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'd215ca08-7a26-4736-86ee-1f7e35215771'	System	23 Sep 2020 16:12:16
User entered 'No interference with activity (1)'	System	23 Sep 2020 16:12:16

FDA-CBER-2022-1614-0508965

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(12)
Generated On: 09 Jun 2021 15:08:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-23T09:12:12', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'd215ca08-7a26-4736-86ee-1f7e35215771'	System	23 Sep 2020 16:12:16
User entered '23 Sep 2020 09:12'	System	23 Sep 2020 16:12:16

FDA-CBER-2022-1614-0508966

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(12)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 04:44:12

FDA-CBER-2022-1614-0508967

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(12)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 04:44:12

FDA-CBER-2022-1614-0508968

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(13)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	23 Sep 2020 16:12:16
User entered 'Day 13'	System	23 Sep 2020 16:12:16

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(13)
Generated On: 09 Jun 2021 15:08:42
Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0508970

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(13)
Generated On: 09 Jun 2021 15:08:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0508971

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(13)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '23 Sep 2020 12:00'	System	23 Sep 2020 16:12:16

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(13)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 16:12:16

FDA-CBER-2022-1614-0508973

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(14)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	23 Sep 2020 16:12:16
User entered 'Day 14'	System	23 Sep 2020 16:12:16

FDA-CBER-2022-1614-0508974

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(14)
Generated On: 09 Jun 2021 15:08:42
Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-24T18:24:58', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'fd4742ae-8345-4c9c-8a3b-e5be137466ae'	System	25 Sep 2020 01:25:10
User entered 'No interference with activity (1)'	System	25 Sep 2020 01:25:10

FDA-CBER-2022-1614-0508975

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(14)
Generated On: 09 Jun 2021 15:08:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-24T18:25:03', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'fd4742ae-8345-4c9c-8a3b-e5be137466ae'	System	25 Sep 2020 01:25:10
User entered '24 Sep 2020 18:25'	System	25 Sep 2020 01:25:10

FDA-CBER-2022-1614-0508976

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(14)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 16:12:16

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(14)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 16:12:16

FDA-CBER-2022-1614-0508978

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(15)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	25 Sep 2020 01:25:10
User entered 'Day 15'	System	25 Sep 2020 01:25:10

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(15)
Generated On: 09 Jun 2021 15:08:42
Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-25T22:28:01', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '520c4309-c87c-41d4-b373-f65568625535'	System	26 Sep 2020 05:28:09
User entered 'No interference with activity (1)'	System	26 Sep 2020 05:28:09

FDA-CBER-2022-1614-0508980

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(15)
Generated On: 09 Jun 2021 15:08:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-25T22:28:06', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '520c4309-c87c-41d4-b373-f65568625535'	System	26 Sep 2020 05:28:09
User entered '25 Sep 2020 22:28'	System	26 Sep 2020 05:28:09

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(15)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '25 Sep 2020 12:00'	System	25 Sep 2020 01:25:10

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(15)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '26 Sep 2020 11:59'	System	25 Sep 2020 01:25:10

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(16)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	25 Sep 2020 01:25:10
User entered 'Day 16'	System	25 Sep 2020 01:25:10

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(16)
Generated On: 09 Jun 2021 15:08:42
Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-26T18:16:02', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '2cc69443-ab73-498d-9881-f82829898412'	System	27 Sep 2020 01:16:16
User entered 'No interference with activity (1)'	System	27 Sep 2020 01:16:16

FDA-CBER-2022-1614-0508985

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(16)
Generated On: 09 Jun 2021 15:08:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-26T18:16:10', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '2cc69443-ab73-498d-9881-f82829898412'	System	27 Sep 2020 01:16:16
User entered '26 Sep 2020 18:16'	System	27 Sep 2020 01:16:16

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(16)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 01:25:10

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(16)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 01:25:10

FDA-CBER-2022-1614-0508988

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(17)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	26 Sep 2020 05:28:09
User entered 'Day 17'	System	26 Sep 2020 05:28:09

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(17)
Generated On: 09 Jun 2021 15:08:42
Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-27T13:28:03', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '80eabd40-156e-4f3d-a8fe-f03293484118'	System	27 Sep 2020 20:28:14
User entered 'Some interference with activity (2)'	System	27 Sep 2020 20:28:14

FDA-CBER-2022-1614-0508990

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(17)
Generated On: 09 Jun 2021 15:08:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-27T13:28:11', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '80eabd40-156e-4f3d-a8fe-f03293484118'	System	27 Sep 2020 20:28:14
User entered '27 Sep 2020 13:28'	System	27 Sep 2020 20:28:14

FDA-CBER-2022-1614-0508991

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(17)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '27 Sep 2020 12:00'	System	26 Sep 2020 05:28:09

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(17)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '28 Sep 2020 11:59'	System	26 Sep 2020 05:28:09

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(18)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	27 Sep 2020 01:16:16
User entered 'Day 18'	System	27 Sep 2020 01:16:16

FDA-CBER-2022-1614-0508994

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(18)
Generated On: 09 Jun 2021 15:08:42
Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0508995

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(18)
Generated On: 09 Jun 2021 15:08:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0508996

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(18)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '28 Sep 2020 12:00'	System	27 Sep 2020 01:16:16

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(18)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '29 Sep 2020 11:59'	System	27 Sep 2020 01:16:16

FDA-CBER-2022-1614-0508998

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(19)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	27 Sep 2020 20:28:14
User entered 'Day 19'	System	27 Sep 2020 20:28:14

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(19)
Generated On: 09 Jun 2021 15:08:42
Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-29T23:14:19', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'f5c46d2d-43b6-43c0-9836-3f5bfd0e7b23'	System	30 Sep 2020 06:14:26
User entered 'No interference with activity (1)'	System	30 Sep 2020 06:14:26

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(19)
Generated On: 09 Jun 2021 15:08:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-29T23:14:23', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'f5c46d2d-43b6-43c0-9836-3f5bfd0e7b23'	System	30 Sep 2020 06:14:26
User entered '29 Sep 2020 23:14'	System	30 Sep 2020 06:14:26

FDA-CBER-2022-1614-0509001

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(19)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '29 Sep 2020 12:00'	System	27 Sep 2020 20:28:14

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(19)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '30 Sep 2020 11:59'	System	27 Sep 2020 20:28:14

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(20)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	30 Sep 2020 06:14:26
User entered 'Day 20'	System	30 Sep 2020 06:14:26

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(20)
Generated On: 09 Jun 2021 15:08:42
Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0509005

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(20)
Generated On: 09 Jun 2021 15:08:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0509006

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(20)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '30 Sep 2020 12:00'	System	30 Sep 2020 06:14:26

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(20)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 06:14:26

FDA-CBER-2022-1614-0509008

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(21)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	30 Sep 2020 06:14:26
User entered 'Day 21'	System	30 Sep 2020 06:14:26

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(21)
Generated On: 09 Jun 2021 15:08:42
Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-10-01T21:14:55', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '465bca4d-0cda-433e-b9c8-cfccfbc0b534'	System	02 Oct 2020 04:15:05
User entered 'None (0)'	System	02 Oct 2020 04:15:05

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(21)
Generated On: 09 Jun 2021 15:08:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-10-01T21:15:01', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '465bca4d-0cda-433e-b9c8-cfccfbc0b534'	System	02 Oct 2020 04:15:05
User entered '01 Oct 2020 21:15'	System	02 Oct 2020 04:15:05

FDA-CBER-2022-1614-0509011

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(21)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 06:14:26

US3112192
Folder: Diary Dose 2 (1)
Form: Fatigue_Day(21)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 06:14:26

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(8)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	16 Sep 2020 22:27:01
User entered 'Day 8'	System	16 Sep 2020 22:27:01

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(8)
Generated On: 09 Jun 2021 15:08:42
Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-19T01:00:03', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'd4ee5893-52a1-468b-8025-b11250d6331a'	System	19 Sep 2020 08:00:10
User entered 'Some interference with activity (2)'	System	19 Sep 2020 08:00:10

FDA-CBER-2022-1614-0509015

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(8)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-19T01:00:07', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'd4ee5893-52a1-468b-8025-b11250d6331a'	System	19 Sep 2020 08:00:10
User entered '19 Sep 2020 01:00'	System	19 Sep 2020 08:00:10

FDA-CBER-2022-1614-0509016

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(8)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 22:27:01

FDA-CBER-2022-1614-0509017

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(8)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 22:27:01

FDA-CBER-2022-1614-0509018

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(9)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	19 Sep 2020 07:58:02
User entered 'Day 9'	System	19 Sep 2020 07:58:02

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(9)
Generated On: 09 Jun 2021 15:08:42
Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-19T18:56:52', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '50a84436-8b0f-4ee6-bfe4-1feba42df920'	System	20 Sep 2020 01:57:04
User entered 'Some interference with activity (2)'	System	20 Sep 2020 01:57:04

FDA-CBER-2022-1614-0509020

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(9)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-19T18:57:00', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '50a84436-8b0f-4ee6-bfe4-1feba42df920'	System	20 Sep 2020 01:57:04
User entered '19 Sep 2020 18:57'	System	20 Sep 2020 01:57:04

FDA-CBER-2022-1614-0509021

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(9)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '19 Sep 2020 12:00'	System	19 Sep 2020 07:58:02

FDA-CBER-2022-1614-0509022

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(9)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '20 Sep 2020 11:59'	System	19 Sep 2020 07:58:02

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(10)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	19 Sep 2020 08:00:10
User entered 'Day 10'	System	19 Sep 2020 08:00:10

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(10)
Generated On: 09 Jun 2021 15:08:42
Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-20T21:44:34', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '01d59b42-0bd7-40ff-80e8-7ca71121b66c'	System	21 Sep 2020 04:45:24
User entered 'No interference with activity (1)'	System	21 Sep 2020 04:45:24

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(10)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-20T21:45:21', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '01d59b42-0bd7-40ff-80e8-7ca71121b66c'	System	21 Sep 2020 04:45:24
User entered '20 Sep 2020 21:45'	System	21 Sep 2020 04:45:24

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(10)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '20 Sep 2020 12:00'	System	19 Sep 2020 08:00:10

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(10)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '21 Sep 2020 11:59'	System	19 Sep 2020 08:00:10

FDA-CBER-2022-1614-0509028

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(11)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	20 Sep 2020 01:57:04
User entered 'Day 11'	System	20 Sep 2020 01:57:04

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(11)
Generated On: 09 Jun 2021 15:08:42
Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(11)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0509031

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(11)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '21 Sep 2020 12:00'	System	20 Sep 2020 01:57:04

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(11)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '22 Sep 2020 11:59'	System	20 Sep 2020 01:57:04

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(12)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	21 Sep 2020 04:45:24
User entered 'Day 12'	System	21 Sep 2020 04:45:24

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(12)
Generated On: 09 Jun 2021 15:08:42
Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-23T09:12:20', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '11f310c5-e403-4d03-a61e-c1523d3d67c9'	System	23 Sep 2020 16:12:29
User entered 'No interference with activity (1)'	System	23 Sep 2020 16:12:29

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(12)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-23T09:12:25', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '11f310c5-e403-4d03-a61e-c1523d3d67c9'	System	23 Sep 2020 16:12:29
User entered '23 Sep 2020 09:12'	System	23 Sep 2020 16:12:29

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(12)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 04:45:24

FDA-CBER-2022-1614-0509037

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(12)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 04:45:24

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(13)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	23 Sep 2020 16:12:29
User entered 'Day 13'	System	23 Sep 2020 16:12:29

FDA-CBER-2022-1614-0509039

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(13)
Generated On: 09 Jun 2021 15:08:42
Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(13)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0509041

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(13)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '23 Sep 2020 12:00'	System	23 Sep 2020 16:12:29

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(13)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 16:12:29

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(14)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	23 Sep 2020 16:12:29
User entered 'Day 14'	System	23 Sep 2020 16:12:29

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(14)
Generated On: 09 Jun 2021 15:08:42
Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-24T18:26:41', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '9b54f2ed-6eec-446a-ac48-e542bd1109ab'	System	25 Sep 2020 01:26:50
User entered 'No interference with activity (1)'	System	25 Sep 2020 01:26:50

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(14)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-24T18:26:47', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '9b54f2ed-6eec-446a-ac48-e542bd1109ab'	System	25 Sep 2020 01:26:50
User entered '24 Sep 2020 18:26'	System	25 Sep 2020 01:26:50

FDA-CBER-2022-1614-0509046

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(14)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 16:12:29

FDA-CBER-2022-1614-0509047

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(14)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 16:12:29

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(15)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	25 Sep 2020 01:26:50
User entered 'Day 15'	System	25 Sep 2020 01:26:50

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(15)
Generated On: 09 Jun 2021 15:08:42
Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-25T22:28:11', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'd8a798dc-d75b-476e-b448-3cb67ed008bf'	System	26 Sep 2020 05:28:16
User entered 'Some interference with activity (2)'	System	26 Sep 2020 05:28:16

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(15)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-25T22:28:15', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'd8a798dc-d75b-476e-b448-3cb67ed008bf'	System	26 Sep 2020 05:28:16
User entered '25 Sep 2020 22:28'	System	26 Sep 2020 05:28:16

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(15)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '25 Sep 2020 12:00'	System	25 Sep 2020 01:26:50

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(15)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '26 Sep 2020 11:59'	System	25 Sep 2020 01:26:50

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(16)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	25 Sep 2020 01:26:50
User entered 'Day 16'	System	25 Sep 2020 01:26:50

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(16)
Generated On: 09 Jun 2021 15:08:42
Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-26T18:16:22', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '15c545cb-c5ab-4fbc-b381-a7bab47f5eb4'	System	27 Sep 2020 01:16:32
User entered 'Some interference with activity (2)'	System	27 Sep 2020 01:16:32

FDA-CBER-2022-1614-0509055

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(16)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-26T18:16:26', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '15c545cb-c5ab-4fbc-b381-a7bab47f5eb4'	System	27 Sep 2020 01:16:32
User entered '26 Sep 2020 18:16'	System	27 Sep 2020 01:16:32

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(16)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 01:26:50

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(16)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 01:26:50

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(17)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	26 Sep 2020 05:28:16
User entered 'Day 17'	System	26 Sep 2020 05:28:16

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(17)
Generated On: 09 Jun 2021 15:08:42
Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-27T13:28:16', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '3f773a2c-c7aa-403b-92a9-74ef18f09b4c'	System	27 Sep 2020 20:28:26
User entered 'Some interference with activity (2)'	System	27 Sep 2020 20:28:26

FDA-CBER-2022-1614-0509060

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(17)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-27T13:28:21', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '3f773a2c-c7aa-403b-92a9-74ef18f09b4c'	System	27 Sep 2020 20:28:26
User entered '27 Sep 2020 13:28'	System	27 Sep 2020 20:28:26

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(17)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '27 Sep 2020 12:00'	System	26 Sep 2020 05:28:16

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(17)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '28 Sep 2020 11:59'	System	26 Sep 2020 05:28:16

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(18)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	27 Sep 2020 01:16:32
User entered 'Day 18'	System	27 Sep 2020 01:16:32

FDA-CBER-2022-1614-0509064

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(18)
Generated On: 09 Jun 2021 15:08:42
Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(18)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0509066

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(18)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '28 Sep 2020 12:00'	System	27 Sep 2020 01:16:32

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(18)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '29 Sep 2020 11:59'	System	27 Sep 2020 01:16:32

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(19)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	27 Sep 2020 20:28:26
User entered 'Day 19'	System	27 Sep 2020 20:28:26

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(19)
Generated On: 09 Jun 2021 15:08:42
Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-29T23:14:32', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'df12ab0a-364e-4a46-8738-e5570fb77194'	System	30 Sep 2020 06:14:39
User entered 'No interference with activity (1)'	System	30 Sep 2020 06:14:39

FDA-CBER-2022-1614-0509070

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(19)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-29T23:14:35', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'df12ab0a-364e-4a46-8738-e5570fb77194'	System	30 Sep 2020 06:14:39
User entered '29 Sep 2020 23:14'	System	30 Sep 2020 06:14:39

FDA-CBER-2022-1614-0509071

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(19)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '29 Sep 2020 12:00'	System	27 Sep 2020 20:28:26

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(19)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '30 Sep 2020 11:59'	System	27 Sep 2020 20:28:26

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(20)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	30 Sep 2020 06:14:39
User entered 'Day 20'	System	30 Sep 2020 06:14:39

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(20)
Generated On: 09 Jun 2021 15:08:42
Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(20)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0509076

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(20)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '30 Sep 2020 12:00'	System	30 Sep 2020 06:14:39

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(20)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 06:14:39

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(21)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	30 Sep 2020 06:14:39
User entered 'Day 21'	System	30 Sep 2020 06:14:39

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(21)
Generated On: 09 Jun 2021 15:08:42
Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-10-01T21:15:07', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'c6c035f8-871e-4f52-a244-e63e62aa0e76'	System	02 Oct 2020 04:15:15
User entered 'No interference with activity (1)'	System	02 Oct 2020 04:15:15

FDA-CBER-2022-1614-0509080

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(21)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-10-01T21:15:10', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'c6c035f8-871e-4f52-a244-e63e62aa0e76'	System	02 Oct 2020 04:15:15
User entered '01 Oct 2020 21:15'	System	02 Oct 2020 04:15:15

FDA-CBER-2022-1614-0509081

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(21)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 06:14:39

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(21)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 06:14:39

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(22)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	02 Oct 2020 04:15:15
User entered 'Day 22'	System	02 Oct 2020 04:15:15

FDA-CBER-2022-1614-0509084

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(22)
Generated On: 09 Jun 2021 15:08:42
Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(22)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0509086

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(22)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '02 Oct 2020 12:00'	System	02 Oct 2020 04:15:15

FDA-CBER-2022-1614-0509087

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(22)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 04:15:15

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(23)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	02 Oct 2020 04:15:15
User entered 'Day 23'	System	02 Oct 2020 04:15:15

FDA-CBER-2022-1614-0509089

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(23)
Generated On: 09 Jun 2021 15:08:42
Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(23)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0509091

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(23)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 04:15:15

FDA-CBER-2022-1614-0509092

US3112192
Folder: Diary Dose 2 (1)
Form: MuscleAche_Day(23)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 04:15:15

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(8)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	16 Sep 2020 22:27:01
User entered 'Day 8'	System	16 Sep 2020 22:27:01

FDA-CBER-2022-1614-0509094

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(8)
Generated On: 09 Jun 2021 15:08:42
Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-19T01:00:20', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '4b392c87-d5e6-49c2-97f0-985ee5c9ebf4'	System	19 Sep 2020 08:00:28
User entered 'Some interference with activity (2)'	System	19 Sep 2020 08:00:28

FDA-CBER-2022-1614-0509095

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(8)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-19T01:00:25', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '4b392c87-d5e6-49c2-97f0-985ee5c9ebf4'	System	19 Sep 2020 08:00:28
User entered '19 Sep 2020 01:00'	System	19 Sep 2020 08:00:28

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(8)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 22:27:01

FDA-CBER-2022-1614-0509097

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(8)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 22:27:01

FDA-CBER-2022-1614-0509098

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(9)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	19 Sep 2020 07:58:02
User entered 'Day 9'	System	19 Sep 2020 07:58:02

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(9)
Generated On: 09 Jun 2021 15:08:42
Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-19T18:57:11', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '9d30da13-37b5-4cc6-8a58-97f567ddc033'	System	20 Sep 2020 01:57:20
User entered 'No interference with activity (1)'	System	20 Sep 2020 01:57:20

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(9)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-19T18:57:17', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '9d30da13-37b5-4cc6-8a58-97f567ddc033'	System	20 Sep 2020 01:57:20
User entered '19 Sep 2020 18:57'	System	20 Sep 2020 01:57:20

FDA-CBER-2022-1614-0509101

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(9)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '19 Sep 2020 12:00'	System	19 Sep 2020 07:58:02

FDA-CBER-2022-1614-0509102

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(9)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '20 Sep 2020 11:59'	System	19 Sep 2020 07:58:02

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(10)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	19 Sep 2020 08:00:28
User entered 'Day 10'	System	19 Sep 2020 08:00:28

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(10)
Generated On: 09 Jun 2021 15:08:42
Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-20T21:45:54', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'a80e5579-0fa7-4376-abdd-9b4cf3f90629'	System	21 Sep 2020 04:47:16
User entered 'Some interference with activity (2)'	System	21 Sep 2020 04:47:16

FDA-CBER-2022-1614-0509105

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(10)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-20T21:47:11', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'a80e5579-0fa7-4376-abdd-9b4cf3f90629'	System	21 Sep 2020 04:47:16
User entered '20 Sep 2020 21:47'	System	21 Sep 2020 04:47:16

FDA-CBER-2022-1614-0509106

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(10)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '20 Sep 2020 12:00'	System	19 Sep 2020 08:00:28

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(10)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '21 Sep 2020 11:59'	System	19 Sep 2020 08:00:28

FDA-CBER-2022-1614-0509108

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(11)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	20 Sep 2020 01:57:20
User entered 'Day 11'	System	20 Sep 2020 01:57:20

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(11)
Generated On: 09 Jun 2021 15:08:42
Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(11)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0509111

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(11)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '21 Sep 2020 12:00'	System	20 Sep 2020 01:57:20

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(11)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '22 Sep 2020 11:59'	System	20 Sep 2020 01:57:20

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(12)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	21 Sep 2020 04:47:16
User entered 'Day 12'	System	21 Sep 2020 04:47:16

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(12)
Generated On: 09 Jun 2021 15:08:42
Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-23T09:12:31', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'f8903514-d9a2-4719-8b51-d7f94aaab3c5'	System	23 Sep 2020 16:12:42
User entered 'No interference with activity (1)'	System	23 Sep 2020 16:12:42

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(12)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-23T09:12:37', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'f8903514-d9a2-4719-8b51-d7f94aaab3c5'	System	23 Sep 2020 16:12:42
User entered '23 Sep 2020 09:12'	System	23 Sep 2020 16:12:42

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(12)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 04:47:16

FDA-CBER-2022-1614-0509117

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(12)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 04:47:16

FDA-CBER-2022-1614-0509118

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(13)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	23 Sep 2020 16:12:42
User entered 'Day 13'	System	23 Sep 2020 16:12:42

FDA-CBER-2022-1614-0509119

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(13)
Generated On: 09 Jun 2021 15:08:42
Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(13)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0509121

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(13)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '23 Sep 2020 12:00'	System	23 Sep 2020 16:12:42

FDA-CBER-2022-1614-0509122

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(13)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 16:12:42

FDA-CBER-2022-1614-0509123

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(14)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	23 Sep 2020 16:12:42
User entered 'Day 14'	System	23 Sep 2020 16:12:42

FDA-CBER-2022-1614-0509124

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(14)
Generated On: 09 Jun 2021 15:08:42
Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-24T18:25:17', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '5e022d20-00db-42de-81ba-af1b6e32d24e'	System	25 Sep 2020 01:25:29
User entered 'Some interference with activity (2)'	System	25 Sep 2020 01:25:29

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(14)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-24T18:25:21', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '5e022d20-00db-42de-81ba-af1b6e32d24e'	System	25 Sep 2020 01:25:29
User entered '24 Sep 2020 18:25'	System	25 Sep 2020 01:25:29

FDA-CBER-2022-1614-0509126

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(14)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 16:12:42

FDA-CBER-2022-1614-0509127

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(14)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 16:12:42

FDA-CBER-2022-1614-0509128

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(15)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	25 Sep 2020 01:25:29
User entered 'Day 15'	System	25 Sep 2020 01:25:29

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(15)
Generated On: 09 Jun 2021 15:08:42
Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-25T22:28:25', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '3f295f73-a7eb-4307-99c6-0feef8b26745'	System	26 Sep 2020 05:28:37
User entered 'Some interference with activity (2)'	System	26 Sep 2020 05:28:37

FDA-CBER-2022-1614-0509130

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(15)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-25T22:28:33', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '3f295f73-a7eb-4307-99c6-0feef8b26745'	System	26 Sep 2020 05:28:37
User entered '25 Sep 2020 22:28'	System	26 Sep 2020 05:28:37

FDA-CBER-2022-1614-0509131

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(15)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '25 Sep 2020 12:00'	System	25 Sep 2020 01:25:29

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(15)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '26 Sep 2020 11:59'	System	25 Sep 2020 01:25:29

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(16)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	25 Sep 2020 01:25:29
User entered 'Day 16'	System	25 Sep 2020 01:25:29

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(16)
Generated On: 09 Jun 2021 15:08:42

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-26T18:16:39', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '5caa1c8a-5d2a-4f6e-ac21-73863d6560b0'	System	27 Sep 2020 01:16:47
User entered 'No interference with activity (1)'	System	27 Sep 2020 01:16:47

FDA-CBER-2022-1614-0509135

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(16)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-26T18:16:43', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '5caa1c8a-5d2a-4f6e-ac21-73863d6560b0'	System	27 Sep 2020 01:16:47
User entered '26 Sep 2020 18:16'	System	27 Sep 2020 01:16:47

FDA-CBER-2022-1614-0509136

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(16)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 01:25:29

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(16)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 01:25:29

FDA-CBER-2022-1614-0509138

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(17)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	26 Sep 2020 05:28:37
User entered 'Day 17'	System	26 Sep 2020 05:28:37

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(17)
Generated On: 09 Jun 2021 15:08:42
Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-27T13:28:29', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'bed91d18-1121-4174-a5a0-7558ffa943f7'	System	27 Sep 2020 20:28:37
User entered 'Some interference with activity (2)'	System	27 Sep 2020 20:28:37

FDA-CBER-2022-1614-0509140

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(17)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-27T13:28:32', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'bed91d18-1121-4174-a5a0-7558ffa943f7'	System	27 Sep 2020 20:28:37
User entered '27 Sep 2020 13:28'	System	27 Sep 2020 20:28:37

FDA-CBER-2022-1614-0509141

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(17)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '27 Sep 2020 12:00'	System	26 Sep 2020 05:28:37

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(17)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '28 Sep 2020 11:59'	System	26 Sep 2020 05:28:37

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(18)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	27 Sep 2020 01:16:47
User entered 'Day 18'	System	27 Sep 2020 01:16:47

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(18)
Generated On: 09 Jun 2021 15:08:42
Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(18)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0509146

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(18)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '28 Sep 2020 12:00'	System	27 Sep 2020 01:16:47

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(18)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '29 Sep 2020 11:59'	System	27 Sep 2020 01:16:47

FDA-CBER-2022-1614-0509148

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(19)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	27 Sep 2020 20:28:37
User entered 'Day 19'	System	27 Sep 2020 20:28:37

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(19)
Generated On: 09 Jun 2021 15:08:42
Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-29T23:14:40', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '4cfb52e3-b95c-4200-9511-e1b0a0fabc8e'	System	30 Sep 2020 06:14:47
User entered 'No interference with activity (1)'	System	30 Sep 2020 06:14:47

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(19)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-29T23:14:45', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '4cfb52e3-b95c-4200-9511-e1b0a0fabc8e'	System	30 Sep 2020 06:14:47
User entered '29 Sep 2020 23:14'	System	30 Sep 2020 06:14:47

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(19)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '29 Sep 2020 12:00'	System	27 Sep 2020 20:28:37

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(19)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '30 Sep 2020 11:59'	System	27 Sep 2020 20:28:37

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(20)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	30 Sep 2020 06:14:47
User entered 'Day 20'	System	30 Sep 2020 06:14:47

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(20)
Generated On: 09 Jun 2021 15:08:42
Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(20)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0509156

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(20)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '30 Sep 2020 12:00'	System	30 Sep 2020 06:14:47

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(20)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 06:14:47

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(21)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	30 Sep 2020 06:14:47
User entered 'Day 21'	System	30 Sep 2020 06:14:47

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(21)
Generated On: 09 Jun 2021 15:08:42
Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-10-01T21:15:26', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '386f6a2e-2278-4204-a0b9-3369f5e27866'	System	02 Oct 2020 04:15:32
User entered 'No interference with activity (1)'	System	02 Oct 2020 04:15:32

FDA-CBER-2022-1614-0509160

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(21)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-10-01T21:15:30', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '386f6a2e-2278-4204-a0b9-3369f5e27866'	System	02 Oct 2020 04:15:32
User entered '01 Oct 2020 21:15'	System	02 Oct 2020 04:15:32

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(21)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 06:14:47

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(21)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 06:14:47

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(22)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	02 Oct 2020 04:15:32
User entered 'Day 22'	System	02 Oct 2020 04:15:32

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(22)
Generated On: 09 Jun 2021 15:08:42
Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(22)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0509166

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(22)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '02 Oct 2020 12:00'	System	02 Oct 2020 04:15:32

FDA-CBER-2022-1614-0509167

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(22)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 04:15:32

FDA-CBER-2022-1614-0509168

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(23)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	02 Oct 2020 04:15:32
User entered 'Day 23'	System	02 Oct 2020 04:15:32

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(23)
Generated On: 09 Jun 2021 15:08:42
Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0509170

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(23)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0509171

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(23)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 04:15:32

FDA-CBER-2022-1614-0509172

US3112192
Folder: Diary Dose 2 (1)
Form: JointsAche_Day(23)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 04:15:32

FDA-CBER-2022-1614-0509173

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(8)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	16 Sep 2020 22:25:53
User entered 'Day 8'	System	16 Sep 2020 22:25:53

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(8)
Generated On: 09 Jun 2021 15:08:42
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-19T01:01:19', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '7d67063f-8f0a-4686-9009-04026580e971'	System	19 Sep 2020 08:01:30
User entered 'Yes (Y)'	System	19 Sep 2020 08:01:30

FDA-CBER-2022-1614-0509175

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(8)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-19T01:01:28', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '7d67063f-8f0a-4686-9009-04026580e971'	System	19 Sep 2020 08:01:30
User entered '19 Sep 2020 01:01'	System	19 Sep 2020 08:01:30

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(8)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 22:25:53

FDA-CBER-2022-1614-0509177

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(8)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 22:25:53

FDA-CBER-2022-1614-0509178

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(9)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	19 Sep 2020 07:58:02
User entered 'Day 9'	System	19 Sep 2020 07:58:02

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(9)
Generated On: 09 Jun 2021 15:08:42
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-19T18:57:25', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '97f62142-84b6-483f-bf4f-27951573ad76'	System	20 Sep 2020 01:57:33
User entered 'No (N)'	System	20 Sep 2020 01:57:33

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(9)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-19T18:57:30', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '97f62142-84b6-483f-bf4f-27951573ad76'	System	20 Sep 2020 01:57:33
User entered '19 Sep 2020 18:57'	System	20 Sep 2020 01:57:33

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(9)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '19 Sep 2020 12:00'	System	19 Sep 2020 07:58:02

FDA-CBER-2022-1614-0509182

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(9)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '20 Sep 2020 11:59'	System	19 Sep 2020 07:58:02

FDA-CBER-2022-1614-0509183

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(10)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	19 Sep 2020 07:59:37
User entered 'Day 10'	System	19 Sep 2020 07:59:37

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(10)
Generated On: 09 Jun 2021 15:08:42
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-20T21:47:38', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '33cad453-86b7-4540-96dd-c8d33bd7545b'	System	21 Sep 2020 04:47:46
User entered 'No (N)'	System	21 Sep 2020 04:47:46

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(10)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-20T21:47:43', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '33cad453-86b7-4540-96dd-c8d33bd7545b'	System	21 Sep 2020 04:47:46
User entered '20 Sep 2020 21:47'	System	21 Sep 2020 04:47:46

FDA-CBER-2022-1614-0509186

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(10)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '20 Sep 2020 12:00'	System	19 Sep 2020 07:59:37

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(10)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '21 Sep 2020 11:59'	System	19 Sep 2020 07:59:37

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(11)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	20 Sep 2020 01:56:30
User entered 'Day 11'	System	20 Sep 2020 01:56:30

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(11)
Generated On: 09 Jun 2021 15:08:42
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(11)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0509191

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(11)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '21 Sep 2020 12:00'	System	20 Sep 2020 01:56:30

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(11)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '22 Sep 2020 11:59'	System	20 Sep 2020 01:56:30

FDA-CBER-2022-1614-0509193

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(12)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	21 Sep 2020 04:39:51
User entered 'Day 12'	System	21 Sep 2020 04:39:51

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(12)
Generated On: 09 Jun 2021 15:08:42
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-23T09:12:43', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'a6b7d0d8-101a-4650-a4f8-281914d78c77'	System	23 Sep 2020 16:12:52
User entered 'No (N)'	System	23 Sep 2020 16:12:52

FDA-CBER-2022-1614-0509195

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(12)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-23T09:12:49', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'a6b7d0d8-101a-4650-a4f8-281914d78c77'	System	23 Sep 2020 16:12:52
User entered '23 Sep 2020 09:12'	System	23 Sep 2020 16:12:52

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(12)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 04:39:51

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(12)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 04:39:51

FDA-CBER-2022-1614-0509198

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(13)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	23 Sep 2020 16:12:07
User entered 'Day 13'	System	23 Sep 2020 16:12:07

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(13)
Generated On: 09 Jun 2021 15:08:42
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(13)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0509201

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(13)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '23 Sep 2020 12:00'	System	23 Sep 2020 16:12:07

FDA-CBER-2022-1614-0509202

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(13)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 16:12:07

FDA-CBER-2022-1614-0509203

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(14)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	23 Sep 2020 16:12:07
User entered 'Day 14'	System	23 Sep 2020 16:12:07

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(14)
Generated On: 09 Jun 2021 15:08:42
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-24T18:25:29', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'dec03ed4-a0e8-4267-92af-e848602dfe6c'	System	25 Sep 2020 01:25:44
User entered 'No (N)'	System	25 Sep 2020 01:25:44

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(14)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-24T18:25:40', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'dec03ed4-a0e8-4267-92af-e848602dfe6c'	System	25 Sep 2020 01:25:44
User entered '24 Sep 2020 18:25'	System	25 Sep 2020 01:25:44

FDA-CBER-2022-1614-0509206

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(14)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 16:12:07

FDA-CBER-2022-1614-0509207

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(14)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 16:12:07

FDA-CBER-2022-1614-0509208

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(15)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	25 Sep 2020 01:25:10
User entered 'Day 15'	System	25 Sep 2020 01:25:10

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(15)
Generated On: 09 Jun 2021 15:08:42
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-25T22:28:41', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'eef51dd9-cab7-4408-b59d-7a7737d9fb6c'	System	26 Sep 2020 05:28:47
User entered 'No (N)'	System	26 Sep 2020 05:28:47

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(15)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-25T22:28:46', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'eef51dd9-cab7-4408-b59d-7a7737d9fb6c'	System	26 Sep 2020 05:28:47
User entered '25 Sep 2020 22:28'	System	26 Sep 2020 05:28:47

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(15)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '25 Sep 2020 12:00'	System	25 Sep 2020 01:25:10

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(15)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '26 Sep 2020 11:59'	System	25 Sep 2020 01:25:10

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(16)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	25 Sep 2020 01:25:10
User entered 'Day 16'	System	25 Sep 2020 01:25:10

FDA-CBER-2022-1614-0509214

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(16)
Generated On: 09 Jun 2021 15:08:42
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-26T18:17:06', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'f0ccbff3-75ea-44f2-80df-a218ef99a8fd'	System	27 Sep 2020 01:17:13
User entered 'No (N)'	System	27 Sep 2020 01:17:13

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(16)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-26T18:17:10', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'f0ccbff3-75ea-44f2-80df-a218ef99a8fd'	System	27 Sep 2020 01:17:13
User entered '26 Sep 2020 18:17'	System	27 Sep 2020 01:17:13

FDA-CBER-2022-1614-0509216

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(16)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 01:25:10

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(16)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 01:25:10

FDA-CBER-2022-1614-0509218

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(17)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	26 Sep 2020 05:27:58
User entered 'Day 17'	System	26 Sep 2020 05:27:58

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(17)
Generated On: 09 Jun 2021 15:08:42
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-27T13:28:41', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'ad75d305-1097-4975-a771-18113723570f'	System	27 Sep 2020 20:28:52
User entered 'No (N)'	System	27 Sep 2020 20:28:52

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(17)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-27T13:28:47', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'ad75d305-1097-4975-a771-18113723570f'	System	27 Sep 2020 20:28:52
User entered '27 Sep 2020 13:28'	System	27 Sep 2020 20:28:52

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(17)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '27 Sep 2020 12:00'	System	26 Sep 2020 05:27:58

FDA-CBER-2022-1614-0509222

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(17)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '28 Sep 2020 11:59'	System	26 Sep 2020 05:27:58

FDA-CBER-2022-1614-0509223

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(18)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	27 Sep 2020 01:15:56
User entered 'Day 18'	System	27 Sep 2020 01:15:56

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(18)
Generated On: 09 Jun 2021 15:08:42
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0509225

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(18)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0509226

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(18)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '28 Sep 2020 12:00'	System	27 Sep 2020 01:15:56

FDA-CBER-2022-1614-0509227

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(18)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '29 Sep 2020 11:59'	System	27 Sep 2020 01:15:56

FDA-CBER-2022-1614-0509228

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(19)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	27 Sep 2020 20:28:14
User entered 'Day 19'	System	27 Sep 2020 20:28:14

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(19)
Generated On: 09 Jun 2021 15:08:42
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-29T23:14:56', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'b2946a11-a92d-4f26-b2dc-2204d7e47d45'	System	30 Sep 2020 06:15:06
User entered 'Yes (Y)'	System	30 Sep 2020 06:15:06

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(19)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-29T23:15:02', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'b2946a11-a92d-4f26-b2dc-2204d7e47d45'	System	30 Sep 2020 06:15:06
User entered '29 Sep 2020 23:15'	System	30 Sep 2020 06:15:06

FDA-CBER-2022-1614-0509231

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(19)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '29 Sep 2020 12:00'	System	27 Sep 2020 20:28:14

FDA-CBER-2022-1614-0509232

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(19)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '30 Sep 2020 11:59'	System	27 Sep 2020 20:28:14

FDA-CBER-2022-1614-0509233

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(20)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	30 Sep 2020 06:14:26
User entered 'Day 20'	System	30 Sep 2020 06:14:26

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(20)
Generated On: 09 Jun 2021 15:08:42
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0509235

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(20)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0509236

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(20)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '30 Sep 2020 12:00'	System	30 Sep 2020 06:14:26

FDA-CBER-2022-1614-0509237

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(20)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '01 Oct 2020 11:59'	System	30 Sep 2020 06:14:26

FDA-CBER-2022-1614-0509238

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(21)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	30 Sep 2020 06:14:26
User entered 'Day 21'	System	30 Sep 2020 06:14:26

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(21)
Generated On: 09 Jun 2021 15:08:42
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-10-01T21:15:37', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '665d1e1c-7f4b-4792-8fab-98c3c8a7f1e2'	System	02 Oct 2020 04:15:46
User entered 'No (N)'	System	02 Oct 2020 04:15:46

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(21)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-10-01T21:15:42', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '665d1e1c-7f4b-4792-8fab-98c3c8a7f1e2'	System	02 Oct 2020 04:15:46
User entered '01 Oct 2020 21:15'	System	02 Oct 2020 04:15:46

FDA-CBER-2022-1614-0509241

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(21)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 06:14:26

FDA-CBER-2022-1614-0509242

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(21)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 06:14:26

FDA-CBER-2022-1614-0509243

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(22)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	02 Oct 2020 04:15:15
User entered 'Day 22'	System	02 Oct 2020 04:15:15

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(22)
Generated On: 09 Jun 2021 15:08:42
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(22)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0509246

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(22)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '02 Oct 2020 12:00'	System	02 Oct 2020 04:15:15

FDA-CBER-2022-1614-0509247

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(22)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 04:15:15

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(23)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	02 Oct 2020 04:15:15
User entered 'Day 23'	System	02 Oct 2020 04:15:15

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(23)
Generated On: 09 Jun 2021 15:08:42
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(23)
Generated On: 09 Jun 2021 15:08:42
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39

FDA-CBER-2022-1614-0509251

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(23)
Generated On: 09 Jun 2021 15:08:42
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 04:15:15

FDA-CBER-2022-1614-0509252

US3112192
Folder: Diary Dose 2 (1)
Form: Medical Attention_Day(23)
Generated On: 09 Jun 2021 15:08:42
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 04:15:15

FDA-CBER-2022-1614-0509253

US3112192
Folder: Diary Dose 2 (1)
Form: Underarm Gland_Day(8)
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	19 Sep 2020 07:58:10
User entered 'Day 8'	System	19 Sep 2020 07:58:10

US3112192
Folder: Diary Dose 2 (1)
Form: Underarm Gland_Day(8)
Generated On: 09 Jun 2021 15:08:42
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-19T01:02:01', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'a3cccb06-58ec-4fb8-b8a7-33fad0b3bfaf'	System	19 Sep 2020 08:02:08
User entered 'None (1)'	System	19 Sep 2020 08:02:08

US3112192
Folder: Diary Dose 2 (1)
Form: Underarm Gland_Day(8)
Generated On: 09 Jun 2021 15:08:42
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-09-19T01:02:06', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'a3cccb06-58ec-4fb8-b8a7-33fad0b3bfaf'	System	19 Sep 2020 08:02:08
User entered '19 Sep 2020 01:02'	System	19 Sep 2020 08:02:08

FDA-CBER-2022-1614-0509256

US3112192
Folder: Diary Dose 2 (1)
Form: Underarm Gland_Day(8)
Generated On: 09 Jun 2021 15:08:42
PC Open Date and Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '18 Sep 2020 12:00'	System	19 Sep 2020 07:58:10

FDA-CBER-2022-1614-0509257

US3112192
Folder: Diary Dose 2 (1)
Form: Underarm Gland_Day(8)
Generated On: 09 Jun 2021 15:08:42
PC Close Date and Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
User entered '19 Sep 2020 11:59'	System	19 Sep 2020 07:58:10

US3112192
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:08:42
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:42:50
User entered 'Yes (Y)'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:58:25

US3112192
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:08:42
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:42:50
User entered '18 Sep 2020'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:58:25

US3112192
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:08:42
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:42:50
User entered 'Contact Made (CONTACT MADE)'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:58:25

US3112192
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:08:42
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:42:50
User entered empty.	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:58:25

US3112192
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:08:42
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:42:50
User entered 'Yes (Y)'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:58:29

US3112192
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:08:42
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User entered '1'	System	18 Sep 2020 19:58:29

US3112192
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:08:42
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	25 Sep 2020 20:04:58

FDA-CBER-2022-1614-0509265

US3112192
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:08:42
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:01:30
User entered '25 Sep 2020'	Karen Mylerberg (b) (4) (b) (4)	25 Sep 2020 20:04:58

US3112192
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:08:42
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:01:30
User entered 'Contact Made (CONTACT MADE)'	Karen Mylerberg (b) (4) (b) (4)	25 Sep 2020 20:04:58

US3112192
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:08:42
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:01:30
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	25 Sep 2020 20:04:58

FDA-CBER-2022-1614-0509268

US3112192
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:08:42
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	25 Sep 2020 20:05:08

US3112192
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:08:42
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User entered '1'	System	25 Sep 2020 20:05:08

US3112192
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:08:42
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	05 Oct 2020 17:22:03

FDA-CBER-2022-1614-0509271

US3112192
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:08:42
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:01:30
User entered '5 Oct 2020'	Karen Mylerberg (b) (4) (b) (4)	05 Oct 2020 17:22:03

US3112192
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:08:42
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:01:30
User entered 'Contact Made (CONTACT MADE)'	Karen Mylerberg (b) (4) (b) (4)	05 Oct 2020 17:22:03

US3112192
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:08:42
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:01:30
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	05 Oct 2020 17:22:03

FDA-CBER-2022-1614-0509274

US3112192
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:08:42
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	05 Oct 2020 17:22:09

FDA-CBER-2022-1614-0509275

US3112192
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:08:42
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User entered '1'	System	05 Oct 2020 17:22:09

US3112192
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:08:42
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 17:01:46

FDA-CBER-2022-1614-0509277

US3112192
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:08:42
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered '9 Oct 2020'	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 17:01:46

FDA-CBER-2022-1614-0509278

US3112192
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:08:42
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:01:30
User entered 'Clinic (Clinic)'	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 17:01:46

US3112192
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:08:42
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User entered 'VISIT3'	System	13 Oct 2020 17:01:46

FDA-CBER-2022-1614-0509280

US3112192
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 17:02:42

FDA-CBER-2022-1614-0509281

US3112192
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered '9 Oct 2020'	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 17:02:42

FDA-CBER-2022-1614-0509282

US3112192
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered '10:21'	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 17:02:42

US3112192
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User entered '9 Oct 2020 10:21'	System	13 Oct 2020 17:02:42

US3112192
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered '98.6' F	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 17:02:42

US3112192
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered 'Oral (Oral)'	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 17:02:42

US3112192
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered empty.	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 17:02:42

US3112192
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered '56'	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 17:02:42

US3112192
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User entered 'bpm'	System	13 Oct 2020 17:02:42

FDA-CBER-2022-1614-0509289

US3112192
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered '14'	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 17:02:42

FDA-CBER-2022-1614-0509290

US3112192
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User entered 'breaths/min'	System	13 Oct 2020 17:02:42

FDA-CBER-2022-1614-0509291

US3112192
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered '138'	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 17:02:42

US3112192
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User entered 'mmHg'	System	13 Oct 2020 17:02:42

FDA-CBER-2022-1614-0509293

US3112192
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered '74'	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 17:02:42

US3112192
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User entered 'mmHg'	System	13 Oct 2020 17:02:42

FDA-CBER-2022-1614-0509295

US3112192
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29

FDA-CBER-2022-1614-0509296

US3112192
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29

FDA-CBER-2022-1614-0509297

US3112192
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 15:08:42
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered 'No (N)'	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 17:03:08

US3112192
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 15:08:42
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered empty.	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 17:03:08

US3112192
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:08:42
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 17:03:36

US3112192
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:08:42
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:01:30
User entered '9 Oct 2020'	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 17:03:36

FDA-CBER-2022-1614-0509301

US3112192
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:08:42
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered '10:50'	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 17:03:36

FDA-CBER-2022-1614-0509302

US3112192
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:08:42
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User entered '9 Oct 2020 10:50'	System	13 Oct 2020 17:03:36

US3112192
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:08:42
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4) (b) (4)	12 Feb 2021 21:01:30
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 17:03:42

FDA-CBER-2022-1614-0509304

US3112192
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:08:42
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User entered '1'	System	13 Oct 2020 17:03:42

US3112192
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:12:45
Data entry locked.	System	11 Aug 2020 19:55:55
User entered 'Day 64'	System	11 Aug 2020 19:55:55

US3112192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:42

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)	24 Apr 2021 09:08:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:12:45

US3112192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:42

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)	24 Apr 2021 09:08:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:12:45

US3112192
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Please 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)	24 Apr 2021 09:08:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:12:45

US3112192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:42

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)	24 Apr 2021 09:08:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:12:45

US3112192
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:12:45

US3112192
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:12:45

US3112192
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:12:45

US3112192
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:12:45

US3112192
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:12:45

US3112192
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:12:45

US3112192
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:12:45

US3112192
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:12:45

US3112192
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:12:45

US3112192
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:12:45

US3112192
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:12:45

US3112192
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:12:45

US3112192
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:12:45

US3112192
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:12:45

US3112192
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:12:45

US3112192
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:12:45

US3112192
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:12:45

US3112192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:42

Please 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)	24 Apr 2021 09:08:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:12:45

US3112192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:42

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)	24 Apr 2021 09:08:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:12:45

US3112192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:42

Please 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)	24 Apr 2021 09:08:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:12:45

US3112192
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:12:45

US3112192
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:12:45
Data entry locked.	System	11 Aug 2020 19:55:55
User entered '11 Oct 2020 00:01'	System	11 Aug 2020 19:55:55

US3112192
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:35
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 04:12:45
Data entry locked.	System	11 Aug 2020 19:55:55
User entered '15 Oct 2020 23:59'	System	11 Aug 2020 19:55:55

US3112192
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	11 Aug 2020 19:55:55
User entered 'Day 71'	System	11 Aug 2020 19:55:55

US3112192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:42

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-10-20T23:18:22', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '928a3190-9451-4a35-8195-e80ead6b2795'	System	21 Oct 2020 06:18:51
User entered 'Yes (Y)'	System	21 Oct 2020 06:18:51

US3112192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:42

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-10-20T23:18:19', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '928a3190-9451-4a35-8195-e80ead6b2795'	System	21 Oct 2020 06:18:51
User entered 'No (N)'	System	21 Oct 2020 06:18:51

US3112192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:42

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)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-10-20T23:18:17', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '928a3190-9451-4a35-8195-e80ead6b2795'	System	21 Oct 2020 06:18:51
User entered 'No (N)'	System	21 Oct 2020 06:18:51

US3112192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:42

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)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-10-20T23:18:15', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '928a3190-9451-4a35-8195-e80ead6b2795'	System	21 Oct 2020 06:18:51
User entered 'Yes (Y)'	System	21 Oct 2020 06:18:51

US3112192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:42

Please 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)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-10-20T23:18:31', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '928a3190-9451-4a35-8195-e80ead6b2795'	System	21 Oct 2020 06:18:51
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	21 Oct 2020 06:18:51

US3112192
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-10-20T23:18:42', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '928a3190-9451-4a35-8195-e80ead6b2795'	System	21 Oct 2020 06:18:51
User entered '20 Oct 2020 23:18:42'	System	21 Oct 2020 06:18:51

US3112192
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	11 Aug 2020 19:55:55
User entered '18 Oct 2020 00:01'	System	11 Aug 2020 19:55:55

US3112192
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	11 Aug 2020 19:55:55
User entered '22 Oct 2020 23:59'	System	11 Aug 2020 19:55:55

US3112192
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	11 Aug 2020 19:55:55
User entered 'Day 78'	System	11 Aug 2020 19:55:55

US3112192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:42

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-10-25T23:19:00', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '0a857492-ba01-463c-9c49-55b219167c3c'	System	26 Oct 2020 06:19:12
User entered 'No (N)'	System	26 Oct 2020 06:19:12

US3112192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:42

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-10-25T23:19:04', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '0a857492-ba01-463c-9c49-55b219167c3c'	System	26 Oct 2020 06:19:12
User entered 'No (N)'	System	26 Oct 2020 06:19:12

US3112192
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-10-25T23:19:11', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '0a857492-ba01-463c-9c49-55b219167c3c'	System	26 Oct 2020 06:19:12
User entered '25 Oct 2020 23:19:11'	System	26 Oct 2020 06:19:12

FDA-CBER-2022-1614-0509346

US3112192
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	11 Aug 2020 19:55:55
User entered '25 Oct 2020 00:01'	System	11 Aug 2020 19:55:55

US3112192
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	11 Aug 2020 19:55:55
User entered '29 Oct 2020 23:59'	System	11 Aug 2020 19:55:55

FDA-CBER-2022-1614-0509348

US3112192
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	11 Aug 2020 19:55:55
User entered 'Day 92'	System	11 Aug 2020 19:55:55

US3112192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:42

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-11-08T20:41:21', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '3b4ff517-447b-4a21-9ae6-9abaff39d24b'	System	09 Nov 2020 04:43:38
User entered 'Yes (Y)'	System	09 Nov 2020 04:43:38

US3112192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:42

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-11-08T20:41:30', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '3b4ff517-447b-4a21-9ae6-9abaff39d24b'	System	09 Nov 2020 04:43:38
User entered 'No (N)'	System	09 Nov 2020 04:43:38

US3112192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:42

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)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-11-08T20:41:37', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '3b4ff517-447b-4a21-9ae6-9abaff39d24b'	System	09 Nov 2020 04:43:38
User entered 'No (N)'	System	09 Nov 2020 04:43:38

US3112192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:42

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)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-11-08T20:43:11', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '3b4ff517-447b-4a21-9ae6-9abaff39d24b'	System	09 Nov 2020 04:43:38
User entered 'No (N)'	System	09 Nov 2020 04:43:38

US3112192
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-11-08T20:43:33', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '3b4ff517-447b-4a21-9ae6-9abaff39d24b'	System	09 Nov 2020 04:43:38
User entered '08 Nov 2020 20:43:33'	System	09 Nov 2020 04:43:38

US3112192
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	11 Aug 2020 19:55:55
User entered '08 Nov 2020 00:01'	System	11 Aug 2020 19:55:55

US3112192
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	11 Aug 2020 19:55:55
User entered '12 Nov 2020 23:59'	System	11 Aug 2020 19:55:55

FDA-CBER-2022-1614-0509356

US3112192
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	11 Aug 2020 19:55:55
User entered 'Day 99'	System	11 Aug 2020 19:55:55

US3112192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:42

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-11-17T18:44:39', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '035aec42-b3be-4417-a1f7-efd3dc836dde'	System	18 Nov 2020 02:45:05
User entered 'No (N)'	System	18 Nov 2020 02:45:05

US3112192

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:42

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-11-17T18:44:47', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '035aec42-b3be-4417-a1f7-efd3dc836dde'	System	18 Nov 2020 02:45:05
User entered 'No (N)'	System	18 Nov 2020 02:45:05

US3112192
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-11-17T18:44:58', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '035aec42-b3be-4417-a1f7-efd3dc836dde'	System	18 Nov 2020 02:45:05
User entered '17 Nov 2020 18:44:58'	System	18 Nov 2020 02:45:05

US3112192
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	11 Aug 2020 19:55:55
User entered '15 Nov 2020 00:01'	System	11 Aug 2020 19:55:55

US3112192
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 22:57:39
Data entry locked.	System	11 Aug 2020 19:55:55
User entered '19 Nov 2020 23:59'	System	11 Aug 2020 19:55:55

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 04:12:45

US3112192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:42

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-11-21T12:46:01', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'f9c37612-9ad1-4af2-883a-e48fa4358342'	System	21 Nov 2020 20:46:23
User entered 'No (N)'	System	21 Nov 2020 20:46:23

US3112192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:42

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-11-21T12:46:11', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'f9c37612-9ad1-4af2-883a-e48fa4358342'	System	21 Nov 2020 20:46:23
User entered 'No (N)'	System	21 Nov 2020 20:46:23

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-11-21T12:46:20', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'f9c37612-9ad1-4af2-883a-e48fa4358342'	System	21 Nov 2020 20:46:23
User entered '21 Nov 2020 12:46:20'	System	21 Nov 2020 20:46:23

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 04:12:45

US3112192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:42

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-11-28T11:08:56', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'cb019957-241c-40a6-b4bd-3200c691a87c'	System	28 Nov 2020 19:09:17
User entered 'No (N)'	System	28 Nov 2020 19:09:17

US3112192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:42

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-11-28T11:09:04', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'cb019957-241c-40a6-b4bd-3200c691a87c'	System	28 Nov 2020 19:09:17
User entered 'No (N)'	System	28 Nov 2020 19:09:17

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-11-28T11:09:13', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'cb019957-241c-40a6-b4bd-3200c691a87c'	System	28 Nov 2020 19:09:17
User entered '28 Nov 2020 11:09:13'	System	28 Nov 2020 19:09:17

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 04:12:45

US3112192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:42

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-12-03T23:16:08', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'ea072e7a-eed7-44ba-becb-c6d2cd0b6fbc'	System	04 Dec 2020 07:16:26
User entered 'No (N)'	System	04 Dec 2020 07:16:26

US3112192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:42

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-12-03T23:15:20', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'ea072e7a-eed7-44ba-becb-c6d2cd0b6fbc'	System	04 Dec 2020 07:16:26
User entered 'No (N)'	System	04 Dec 2020 07:16:26

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-12-03T23:16:23', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'ea072e7a-eed7-44ba-becb-c6d2cd0b6fbc'	System	04 Dec 2020 07:16:26
User entered '03 Dec 2020 23:16:23'	System	04 Dec 2020 07:16:26

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 04:12:45

US3112192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:42

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-12-13T22:17:55', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '78745086-3d9a-4b8d-af63-e96f874872c6'	System	14 Dec 2020 06:18:12
User entered 'No (N)'	System	14 Dec 2020 06:18:12

US3112192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:42

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-12-13T22:18:02', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '78745086-3d9a-4b8d-af63-e96f874872c6'	System	14 Dec 2020 06:18:12
User entered 'No (N)'	System	14 Dec 2020 06:18:12

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-12-13T22:18:08', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '78745086-3d9a-4b8d-af63-e96f874872c6'	System	14 Dec 2020 06:18:12
User entered '13 Dec 2020 22:18:08'	System	14 Dec 2020 06:18:12

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 04:12:45

US3112192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:42

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-12-17T21:52:33', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '3eef3b23-1f8b-4142-8827-93275971e55f'	System	18 Dec 2020 05:53:09
User entered 'No (N)'	System	18 Dec 2020 05:53:09

US3112192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:42

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-12-17T21:52:52', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '3eef3b23-1f8b-4142-8827-93275971e55f'	System	18 Dec 2020 05:53:09
User entered 'No (N)'	System	18 Dec 2020 05:53:09

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-12-17T21:53:06', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '3eef3b23-1f8b-4142-8827-93275971e55f'	System	18 Dec 2020 05:53:09
User entered '17 Dec 2020 21:53:06'	System	18 Dec 2020 05:53:09

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 04:12:45

US3112192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:42

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-12-27T17:41:27', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'b03d37be-821b-4b90-8b55-766ba5160c1d'	System	28 Dec 2020 01:41:45
User entered 'No (N)'	System	28 Dec 2020 01:41:45

US3112192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:42

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-12-27T17:41:35', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'b03d37be-821b-4b90-8b55-766ba5160c1d'	System	28 Dec 2020 01:41:45
User entered 'No (N)'	System	28 Dec 2020 01:41:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2020-12-27T17:41:41', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'b03d37be-821b-4b90-8b55-766ba5160c1d'	System	28 Dec 2020 01:41:45
User entered '27 Dec 2020 17:41:41'	System	28 Dec 2020 01:41:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 04:12:45

US3112192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:42

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2021-01-03T22:02:58', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'f68065a5-a9fe-40bd-bd6b-c4b992f5e8f8'	System	04 Jan 2021 06:03:17
User entered 'No (N)'	System	04 Jan 2021 06:03:17

US3112192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:42

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2021-01-03T22:03:06', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'f68065a5-a9fe-40bd-bd6b-c4b992f5e8f8'	System	04 Jan 2021 06:03:17
User entered 'No (N)'	System	04 Jan 2021 06:03:17

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2021-01-03T22:03:13', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'f68065a5-a9fe-40bd-bd6b-c4b992f5e8f8'	System	04 Jan 2021 06:03:17
User entered '03 Jan 2021 22:03:13'	System	04 Jan 2021 06:03:17

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 04:12:45

US3112192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:42

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2021-01-18T07:40:15', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'f5d85384-a93d-41cf-afbc-7d98022937f2'	System	18 Jan 2021 15:40:28
User entered 'No (N)'	System	18 Jan 2021 15:40:28

US3112192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:42

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2021-01-18T07:40:20', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'f5d85384-a93d-41cf-afbc-7d98022937f2'	System	18 Jan 2021 15:40:28
User entered 'No (N)'	System	18 Jan 2021 15:40:28

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2021-01-18T07:40:25', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'f5d85384-a93d-41cf-afbc-7d98022937f2'	System	18 Jan 2021 15:40:28
User entered '18 Jan 2021 07:40:25'	System	18 Jan 2021 15:40:28

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 04:12:45

US3112192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:42

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2021-01-24T21:14:59', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'bc0c1e80-a87f-4e32-a8b1-93eca5f7e350'	System	25 Jan 2021 05:15:16
User entered 'No (N)'	System	25 Jan 2021 05:15:16

US3112192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:42

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2021-01-24T21:15:04', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'bc0c1e80-a87f-4e32-a8b1-93eca5f7e350'	System	25 Jan 2021 05:15:16
User entered 'No (N)'	System	25 Jan 2021 05:15:16

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2021-01-24T21:15:11', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'bc0c1e80-a87f-4e32-a8b1-93eca5f7e350'	System	25 Jan 2021 05:15:16
User entered '24 Jan 2021 21:15:11'	System	25 Jan 2021 05:15:16

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 04:12:45

US3112192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:42

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2021-01-31T23:09:38', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '02f56b65-31c6-41b7-acf8-35083c9105b2'	System	01 Feb 2021 07:10:04
User entered 'No (N)'	System	01 Feb 2021 07:10:04

US3112192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:42

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2021-01-31T23:09:55', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '02f56b65-31c6-41b7-acf8-35083c9105b2'	System	01 Feb 2021 07:10:04
User entered 'No (N)'	System	01 Feb 2021 07:10:04

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2021-01-31T23:10:00', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '02f56b65-31c6-41b7-acf8-35083c9105b2'	System	01 Feb 2021 07:10:04
User entered '31 Jan 2021 23:10:00'	System	01 Feb 2021 07:10:04

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 04:12:45

US3112192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:42

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2021-03-01T19:49:46-08:00', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '2753c242-bfbb-4005-bc7a-bde1173bfbac'	System	02 Mar 2021 03:52:43
User entered 'No (N)'	System	02 Mar 2021 03:52:43

US3112192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:42

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2021-03-01T19:49:58-08:00', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '2753c242-bfbb-4005-bc7a-bde1173bfbac'	System	02 Mar 2021 03:52:43
User entered 'No (N)'	System	02 Mar 2021 03:52:43

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2021-03-01T19:50:05-08:00', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '2753c242-bfbb-4005-bc7a-bde1173bfbac'	System	02 Mar 2021 03:52:43
User entered '01 Mar 2021 19:50:05'	System	02 Mar 2021 03:52:43

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 04:12:45

US3112192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:42

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2021-03-06T09:12:29-08:00', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'ef84766a-d830-42b6-bcf4-6d75867f10c4'	System	06 Mar 2021 17:17:50
User entered 'No (N)'	System	06 Mar 2021 17:17:50

US3112192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:42

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2021-03-06T09:12:37-08:00', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'ef84766a-d830-42b6-bcf4-6d75867f10c4'	System	06 Mar 2021 17:17:50
User entered 'No (N)'	System	06 Mar 2021 17:17:50

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2021-03-06T09:12:42-08:00', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: 'ef84766a-d830-42b6-bcf4-6d75867f10c4'	System	06 Mar 2021 17:17:50
User entered '06 Mar 2021 09:12:42'	System	06 Mar 2021 17:17:50

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 04:12:45

US3112192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:42

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2021-03-15T18:16:38-07:00', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '6f39fd38-809f-423a-a9ea-e3448391b69a'	System	16 Mar 2021 01:20:15
User entered 'No (N)'	System	16 Mar 2021 01:20:15

US3112192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:42

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2021-03-15T18:16:47-07:00', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '6f39fd38-809f-423a-a9ea-e3448391b69a'	System	16 Mar 2021 01:20:15
User entered 'No (N)'	System	16 Mar 2021 01:20:15

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2021-03-15T18:16:56-07:00', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '6f39fd38-809f-423a-a9ea-e3448391b69a'	System	16 Mar 2021 01:20:15
User entered '15 Mar 2021 18:16:56'	System	16 Mar 2021 01:20:15

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 04:12:45

US3112192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:42

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2021-03-20T10:06:34-07:00', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '6277f51a-3e2b-4e7a-9487-b2be37be0a68'	System	20 Mar 2021 17:08:01
User entered 'No (N)'	System	20 Mar 2021 17:08:01

US3112192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:42

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2021-03-20T10:06:38-07:00', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '6277f51a-3e2b-4e7a-9487-b2be37be0a68'	System	20 Mar 2021 17:08:01
User entered 'No (N)'	System	20 Mar 2021 17:08:01

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2021-03-20T10:06:44-07:00', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '6277f51a-3e2b-4e7a-9487-b2be37be0a68'	System	20 Mar 2021 17:08:01
User entered '20 Mar 2021 10:06:44'	System	20 Mar 2021 17:08:01

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 04:12:45

US3112192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:42

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2021-04-03T20:10:08-07:00', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '5c676fff-7a58-4eab-9b9e-1ee9acad53c9'	System	04 Apr 2021 03:10:23
User entered 'No (N)'	System	04 Apr 2021 03:10:23

US3112192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:42

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2021-04-03T20:10:15-07:00', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '5c676fff-7a58-4eab-9b9e-1ee9acad53c9'	System	04 Apr 2021 03:10:23
User entered 'No (N)'	System	04 Apr 2021 03:10:23

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2021-04-03T20:10:19-07:00', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '5c676fff-7a58-4eab-9b9e-1ee9acad53c9'	System	04 Apr 2021 03:10:23
User entered '03 Apr 2021 20:10:19'	System	04 Apr 2021 03:10:23

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 04:12:45

US3112192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:42

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2021-04-08T18:15:31-07:00', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '870f2ba5-952c-43fa-b665-c387a34344cd'	System	09 Apr 2021 01:19:17
User entered 'Yes (Y)'	System	09 Apr 2021 01:19:17

US3112192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:42

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2021-04-08T18:15:35-07:00', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '870f2ba5-952c-43fa-b665-c387a34344cd'	System	09 Apr 2021 01:19:17
User entered 'No (N)'	System	09 Apr 2021 01:19:17

US3112192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:42

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2021-04-08T18:15:39-07:00', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '870f2ba5-952c-43fa-b665-c387a34344cd'	System	09 Apr 2021 01:19:17
User entered 'No (N)'	System	09 Apr 2021 01:19:17

US3112192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:42

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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2021-04-08T18:16:03-07:00', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '870f2ba5-952c-43fa-b665-c387a34344cd'	System	09 Apr 2021 01:19:17
User entered 'Yes (Y)'	System	09 Apr 2021 01:19:17

US3112192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:42

Please 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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2021-04-08T18:16:12-07:00', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '870f2ba5-952c-43fa-b665-c387a34344cd'	System	09 Apr 2021 01:19:17
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	09 Apr 2021 01:19:17

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2021-04-08T18:16:20-07:00', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '870f2ba5-952c-43fa-b665-c387a34344cd'	System	09 Apr 2021 01:19:17
User entered '08 Apr 2021 18:16:20'	System	09 Apr 2021 01:19:17

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 04:12:45

US3112192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:42

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2021-04-23T19:32:50-07:00', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '43222a7a-e068-4757-9eac-90f096a73680'	System	24 Apr 2021 02:33:22
User entered 'No (N)'	System	24 Apr 2021 02:33:22

US3112192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:42

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2021-04-23T19:33:08-07:00', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '43222a7a-e068-4757-9eac-90f096a73680'	System	24 Apr 2021 02:33:22
User entered 'No (N)'	System	24 Apr 2021 02:33:22

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2021-04-23T19:33:18-07:00', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '43222a7a-e068-4757-9eac-90f096a73680'	System	24 Apr 2021 02:33:22
User entered '23 Apr 2021 19:33:18'	System	24 Apr 2021 02:33:22

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 04:12:45

US3112192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:42

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2021-04-30T23:16:35-07:00', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '64a59b5b-809c-4cde-bb99-1e1b4ef64c76'	System	01 May 2021 06:16:51
User entered 'No (N)'	System	01 May 2021 06:16:51

US3112192

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:08:42

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2021-04-30T23:16:39-07:00', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '64a59b5b-809c-4cde-bb99-1e1b4ef64c76'	System	01 May 2021 06:16:51
User entered 'No (N)'	System	01 May 2021 06:16:51

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2021-04-30T23:16:47-07:00', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '64a59b5b-809c-4cde-bb99-1e1b4ef64c76'	System	01 May 2021 06:16:51
User entered '30 Apr 2021 23:16:47'	System	01 May 2021 06:16:51

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 04:12:45

US3112192
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 15:08:42
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:12:45
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 04:12:45

US3112192

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:08:42

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2021-03-01T19:50:20-08:00', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '13655573-9efe-44e6-848d-99db6433da68'	System	02 Mar 2021 03:52:59
User entered 'No (N)'	System	02 Mar 2021 03:52:59

US3112192
Folder: Cosmetic Injections and Dermal Fillers
Form: Cosmetic Injection_ Dermal Filler eDiary (1)
Generated On: 09 Jun 2021 15:08:42
Date & Time of Submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:08:35
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (626a384495599773)', Time: '2021-03-01T19:50:27-08:00', User OID: 'PatientReportedOutcome (US3112192)', ODM File OID: '13655573-9efe-44e6-848d-99db6433da68'	System	02 Mar 2021 03:52:59
User entered '01 Mar 2021 19:50:27'	System	02 Mar 2021 03:52:59

FDA-CBER-2022-1614-0509721

US3112192
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:08:42
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:49:39
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	06 Nov 2020 18:09:25

FDA-CBER-2022-1614-0509722

US3112192
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:08:42
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:49:39
User entered '06 Nov 2020'	Matthew Musikanth (b) (4)	06 Nov 2020 18:09:25

US3112192
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:08:42
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:49:39
User entered 'Contact Made (CONTACT MADE)'	Matthew Musikanth (b) (4)	06 Nov 2020 18:09:25

FDA-CBER-2022-1614-0509724

US3112192
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:08:42
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:49:39
User entered empty.	Matthew Musikanth (b) (4)	06 Nov 2020 18:09:25

US3112192
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:08:42
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:49:39
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	06 Nov 2020 18:09:30

FDA-CBER-2022-1614-0509726

US3112192
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:08:42
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:17:29
User entered '1'	System	06 Nov 2020 18:09:30

US3112192
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:08:42
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:13:55
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	11 Dec 2020 16:59:56

US3112192
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:08:42
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:13:55
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '10 Dec 2020'	Matthew Musikanth (b) (4)	11 Dec 2020 16:59:56

US3112192
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:08:42
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:13:55
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered 'Contact Made (CONTACT MADE)'	Matthew Musikanth (b) (4)	11 Dec 2020 16:59:56

US3112192
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:08:42
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:13:55
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered empty.	Matthew Musikanth (b) (4)	11 Dec 2020 16:59:56

US3112192
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:08:42
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:13:55
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	16 Dec 2020 23:00:29

US3112192
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:08:42
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:13:55
User entered '1'	System	16 Dec 2020 23:00:29

US3112192
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:08:42
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:13:55
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	25 Feb 2021 17:45:37

US3112192
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:08:42
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:13:55
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '11 Jan 2021'	Karen Mylerberg (b) (4) (b) (4)	25 Feb 2021 17:45:37

FDA-CBER-2022-1614-0509735

US3112192
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:08:42
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:13:55
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered 'Contact Made (CONTACT MADE)'	Karen Mylerberg (b) (4) (b) (4)	25 Feb 2021 17:45:37

US3112192
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:08:42
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:13:55
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	25 Feb 2021 17:45:37

US3112192
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:08:42
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:13:55
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	22 Feb 2021 21:11:14

FDA-CBER-2022-1614-0509738

US3112192
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:08:42
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:13:55
User entered '1'	System	22 Feb 2021 21:11:14

FDA-CBER-2022-1614-0509739

US3112192
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:08:42
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:13:55
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	22 Feb 2021 21:11:25

US3112192
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:08:42
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:13:55
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '9 Feb 2021'	Natalie Moy (b) (4) (b) (4)	22 Feb 2021 21:11:25

FDA-CBER-2022-1614-0509741

US3112192
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:08:42
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:13:55
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered 'Contact Made (CONTACT MADE)'	Natalie Moy (b) (4) (b) (4)	22 Feb 2021 21:11:25

US3112192
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:08:42
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:13:55
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered empty.	Natalie Moy (b) (4) (b) (4)	22 Feb 2021 21:11:25

US3112192
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:08:42
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:13:55
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	22 Feb 2021 21:11:30

US3112192
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:08:42
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:13:55
User entered '1'	System	22 Feb 2021 21:11:30

US3112192
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:08:42
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:13:55
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	10 Mar 2021 22:03:01

US3112192
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:08:42
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:13:55
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User closed query 'Per CDM: Visit 4 Day 209 and OL-D 57 are both dated 10 Mar 2021. However, the data on the Vital signs forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 05:19:13
Query 'Per CDM: Visit 4 Day 209 and OL-D 57 are both dated 10 Mar 2021. However, the data on the Vital signs forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile.' answered with 'updated' (Site from DM).	Brenda Grande (b) (4) (b) (4)	30 Mar 2021 23:11:43
User opened query 'Per CDM: Visit 4 Day 209 and OL-D 57 are both dated 10 Mar 2021. However, the data on the Vital signs forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 06:40:54
User entered '10 Mar 2021'	Brenda Grande (b) (4) (b) (4)	10 Mar 2021 22:03:01

FDA-CBER-2022-1614-0509747

US3112192
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:08:42
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:13:55
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered 'Clinic (Clinic)'	Brenda Grande (b) (4) (b) (4)	10 Mar 2021 22:03:01

FDA-CBER-2022-1614-0509748

US3112192
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:08:42
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:13:55
User entered 'VISIT4'	System	10 Mar 2021 22:03:01

FDA-CBER-2022-1614-0509749

US3112192
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:13:55
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Mar 2021 19:03:32

FDA-CBER-2022-1614-0509750

US3112192
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:13:55
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '10 Mar 2021'	(b) (4), (b) (6)	30 Mar 2021 19:03:32

FDA-CBER-2022-1614-0509751

US3112192
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:13:55
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '11:25'	(b) (4), (b) (6)	30 Mar 2021 19:03:32

FDA-CBER-2022-1614-0509752

US3112192
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:13:55
User entered '10 Mar 2021 11:25'	System	30 Mar 2021 19:03:32

FDA-CBER-2022-1614-0509753

US3112192
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:13:55
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '98.6' F	(b) (4), (b) (6)	30 Mar 2021 19:03:32

US3112192
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:13:55
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered 'Oral (Oral)'	(b) (4), (b) (6)	30 Mar 2021 19:03:32

FDA-CBER-2022-1614-0509755

US3112192
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:13:55
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 19:03:32

FDA-CBER-2022-1614-0509756

US3112192
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:13:55
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '71'	(b) (4), (b) (6)	30 Mar 2021 19:03:32

FDA-CBER-2022-1614-0509757

US3112192
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:13:55
User entered 'bpm'	System	30 Mar 2021 19:03:32

FDA-CBER-2022-1614-0509758

US3112192
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:13:55
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '16'	(b) (4), (b) (6)	30 Mar 2021 19:03:32

FDA-CBER-2022-1614-0509759

US3112192
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:13:55
User entered 'breaths/min'	System	30 Mar 2021 19:03:32

FDA-CBER-2022-1614-0509760

US3112192
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:13:55
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '122'	(b) (4), (b) (6)	30 Mar 2021 19:03:32

FDA-CBER-2022-1614-0509761

US3112192
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:13:55
User entered 'mmHg'	System	30 Mar 2021 19:03:32

FDA-CBER-2022-1614-0509762

US3112192
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:13:55
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '65'	(b) (4), (b) (6)	30 Mar 2021 19:03:32

FDA-CBER-2022-1614-0509763

US3112192
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:13:55
User entered 'mmHg'	System	30 Mar 2021 19:03:32

FDA-CBER-2022-1614-0509764

US3112192
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:13:55

FDA-CBER-2022-1614-0509765

US3112192
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:13:55

FDA-CBER-2022-1614-0509766

US3112192
Folder: Visit 4 Day 209 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 15:08:42
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:13:55
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered 'No (N)'	Brenda Grande (b) (4) (b) (4)	10 Mar 2021 22:03:16

US3112192
Folder: Visit 4 Day 209 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 15:08:42
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:13:55
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered empty.	Brenda Grande (b) (4) (b) (4)	10 Mar 2021 22:03:16

FDA-CBER-2022-1614-0509768

US3112192
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:08:42
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:13:55
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	10 Mar 2021 22:03:31

US3112192
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:08:42
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:13:55
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '10 Mar 2021'	Brenda Grande (b) (4) (b) (4)	10 Mar 2021 22:03:31

US3112192
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:08:42
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:13:55
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '11:35'	Brenda Grande (b) (4) (b) (4)	10 Mar 2021 22:03:31

US3112192
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:08:42
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:13:55
User entered '10 Mar 2021 11:35'	System	10 Mar 2021 22:03:31

FDA-CBER-2022-1614-0509772

US3112192
Folder: Visit 4 Day 209 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:08:42
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:13:55
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	10 Mar 2021 22:03:54

US3112192
Folder: Visit 4 Day 209 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:08:42
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 07:13:55
User entered '1'	System	10 Mar 2021 22:03:54

US3112192
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:08:42
Was Contact Attempted?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	15 Apr 2021 23:36:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Apr 2021 21:08:24

US3112192
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:08:42
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	15 Apr 2021 23:36:03
User entered '9 Apr 2021'	(b) (4), (b) (6)	09 Apr 2021 21:08:24

US3112192
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:08:42
Please select one status for the follow-up contact

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	15 Apr 2021 23:36:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	09 Apr 2021 21:08:24

US3112192
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:08:42
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	15 Apr 2021 23:36:03
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 21:08:24

US3112192
Folder: Safety Call Day 239 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:08:42
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	15 Apr 2021 23:36:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Apr 2021 21:08:40

US3112192
Folder: Safety Call Day 239 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:08:42
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	09 Apr 2021 21:08:40

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:08:42
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 22:44:49

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:08:42
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '5 Jan 2021'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 22:44:49

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:08:42
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered 'Clinic (Clinic)'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 22:44:49

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:08:42
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User entered 'UNBLND_DECIDE'	System	05 Jan 2021 22:44:49

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 15:08:42
Date of updated informed consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User closed query 'Per sponsor review, This field relates to Amendment 6. The Amendment 6 consent form was not available until 29DEC2020. Please review and update field to the date the subject signed the Amendment 6 or later consent form. If the subject was unblinded and discontinued under Amendment 5, please tick the box below indicating that the consent field is N/A and the subject was unblinded and discontinued under Amendment 5.' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 10:39:01
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 17:21:43
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 14:49:26
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:06:59
Query 'Per sponsor review, This field relates to Amendment 6. The Amendment 6 consent form was not available until 29DEC2020. Please review and update field to the date the subject signed the Amendment 6 or later consent form. If the subject was unblinded and discontinued under Amendment 5, please tick the box below indicating that the consent field is N/A and the subject was unblinded and discontinued under Amendment 5.' answered with 'updated' (Site from DM).	Brenda Grande (b) (4) (b) (4)	07 Apr 2021 18:10:25
Signature has been broken.	Brenda Grande (b) (4) (b) (4)	07 Apr 2021 18:10:09
User entered '5 Jan 2021' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	07 Apr 2021 18:10:09
User opened query 'Per sponsor review, This field relates to Amendment 6. The Amendment 6 consent form was not available until 29DEC2020. Please review and update field to the date the subject signed the Amendment 6 or later consent form. If the subject was unblinded and discontinued under Amendment 5, please tick the box below indicating that the consent field is N/A and the subject was unblinded and discontinued under Amendment 5.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 17:27:14

FDA-CBER-2022-1614-0509785

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 15:08:42
Date of updated informed consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '24 Dec 2020'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 22:45:31

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 15:08:42
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 17:21:45
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 14:49:26
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:06:59
User entered '0'	Brenda Grande (b) (4) (b) (4)	07 Apr 2021 18:10:09
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:16:20

FDA-CBER-2022-1614-0509787

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 15:08:42
Was the participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 17:21:51
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 14:49:26
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 22:45:31

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 15:08:42
Under what version of the Protocol was the Participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 17:21:53
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 14:49:26
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	09 Apr 2021 00:06:59
User entered 'Amendment 6 or later (Amendment 6 or later)'	Brenda Grande (b) (4) (b) (4)	07 Apr 2021 18:10:09
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:16:20

FDA-CBER-2022-1614-0509789

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 15:08:42
Date of unblinding *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 17:21:56
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 14:49:26
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '5 Jan 2021'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 22:45:31

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 15:08:42
Participant randomization assignment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 17:21:57
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 14:49:26
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered 'Placebo (Placebo)'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 22:45:31

FDA-CBER-2022-1614-0509791

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 15:08:42
Actual Dose 1

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 17:21:59
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 14:49:26
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 06:59:07
User entered 'Placebo (Placebo)'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 22:45:31

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 15:08:42
Actual Dose 2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 17:22:01
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 14:49:26
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 06:59:07
User entered 'Placebo (Placebo)'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 22:45:31

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 15:08:42
Will participant receive mRNA-1273?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
DataPoint Un-verified.	(b) (4), (b) (6)	09 Apr 2021 17:22:03
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 14:49:26
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 22:45:31

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 15:08:42
Placebo Only Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User entered '1'	System	05 Jan 2021 22:45:31

FDA-CBER-2022-1614-0509795

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 15:08:42
Continuing with mRNA-1273

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User entered '1'	System	05 Jan 2021 22:45:31

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:08:42
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered missing code ND - Not Done.	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 22:50:14

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:08:42
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered missing code ND - Not Done.	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 22:50:14

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:08:42
BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User entered empty.	System	05 Jan 2021 22:50:14
DataPoint set to visible.	System	05 Jan 2021 22:45:31

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:08:42
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered missing code ND - Not Done.	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 22:50:14

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:08:42
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered missing code ND - Not Done.	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 22:50:14

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:08:42
BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User entered empty.	System	05 Jan 2021 22:50:14
DataPoint set to visible.	System	05 Jan 2021 22:45:31

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:08:42
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User accepted default value 'Pre-Dose (PREDOSE)'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 22:50:14

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:08:42
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 22:50:14

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:08:42
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '5 Jan 2021'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 22:50:14

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:08:42
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '11:09'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 22:50:14

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:08:42
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User entered '5 Jan 2021 11:09'	System	05 Jan 2021 22:50:14

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:08:42
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '99.5' F	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 22:50:14

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:08:42
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered 'Oral (Oral)'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 22:50:14

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:08:42
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered empty.	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 22:50:14

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:08:42
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '52'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 22:50:14

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:08:42
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User entered 'bpm'	System	05 Jan 2021 22:50:14

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:08:42
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '16'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 22:50:14

FDA-CBER-2022-1614-0509813

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:08:42
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User entered 'breaths/min'	System	05 Jan 2021 22:50:14

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:08:42
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '157'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 22:50:14

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:08:42
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User entered 'mmHg'	System	05 Jan 2021 22:50:14

FDA-CBER-2022-1614-0509816

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:08:42
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '81'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 22:50:14

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:08:42
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User entered 'mmHg'	System	05 Jan 2021 22:50:14

FDA-CBER-2022-1614-0509818

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:08:42
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered missing code ND - Not Done.	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 22:50:14

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:08:42
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered missing code ND - Not Done.	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 22:50:14

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 15:08:42
BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User entered empty.	System	05 Jan 2021 22:50:14
DataPoint set to visible.	System	05 Jan 2021 22:45:31

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:08:42
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User accepted default value 'Post-Dose (POSTDOSE)'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 22:51:57

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:08:42
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 22:51:57

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:08:42
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '5 Jan 2021'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 22:51:57

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:08:42
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '12:16'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 22:51:57

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:08:42
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User entered '5 Jan 2021 12:16'	System	05 Jan 2021 22:51:57

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:08:42
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '98.7' F	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 22:51:57

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:08:42
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered 'Oral (Oral)'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 22:51:57

FDA-CBER-2022-1614-0509828

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:08:42
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered empty.	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 22:51:57

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:08:42
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '60'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 22:51:57

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:08:42
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User entered 'bpm'	System	05 Jan 2021 22:51:57

FDA-CBER-2022-1614-0509831

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:08:42
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '16'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 22:51:57

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:08:42
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User entered 'breaths/min'	System	05 Jan 2021 22:51:57

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:08:42
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '138'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 22:51:57

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:08:42
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User entered 'mmHg'	System	05 Jan 2021 22:51:57

FDA-CBER-2022-1614-0509835

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:08:42
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '78'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 22:51:57

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:08:42
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User entered 'mmHg'	System	05 Jan 2021 22:51:57

FDA-CBER-2022-1614-0509837

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 15:08:42
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 22:52:05

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 15:08:42
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '5 Jan 2021'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 22:52:05

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:08:42
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 22:52:41

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:08:42
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered empty.	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 22:52:41

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:08:42
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)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered empty.	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 22:52:41

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:08:42
What was the study treatment? (Unblinded)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User entered 'mRNA-1273'	System	05 Jan 2021 22:52:41
DataPoint set to visible.	System	05 Jan 2021 22:45:31

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:08:42
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '5 Jan 2021'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 22:52:41

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:08:42
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '11:45'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 22:52:41

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:08:42
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User entered '5 Jan 2021 11:45'	System	05 Jan 2021 22:52:41

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:08:42
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered 'Right Arm (RIGHT ARM)'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 22:52:41

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:08:42
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User entered 'ONCE'	System	05 Jan 2021 22:52:41

FDA-CBER-2022-1614-0509848

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:08:42
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User entered 'INTRAMUSCULAR'	System	05 Jan 2021 22:52:41

FDA-CBER-2022-1614-0509849

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:08:42
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 22:55:13

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:08:42
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '5 Jan 2021'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 22:55:13

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:08:42
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '11:30'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 22:55:13

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:08:42
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User entered '5 Jan 2021 11:30'	System	05 Jan 2021 22:55:13

FDA-CBER-2022-1614-0509853

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 09 Jun 2021 15:08:42
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 22:55:46

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 09 Jun 2021 15:08:42
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '5 Jan 2021'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 22:55:46

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 09 Jun 2021 15:08:42
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '11:12'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 22:55:46

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 09 Jun 2021 15:08:42
Collection Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User entered '5 Jan 2021 11:12'	System	05 Jan 2021 22:55:46

FDA-CBER-2022-1614-0509857

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:08:42
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	05 Jan 2021 22:55:51

US3112192
Folder: Participant Decision Visit / OL-D1 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:08:42
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User entered '1'	System	05 Jan 2021 22:55:51

US3112192
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:08:42
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	13 Jan 2021 22:58:45

US3112192
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:08:42
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '12 Jan 2021'	Karen Mylerberg (b) (4) (b) (4)	13 Jan 2021 22:58:45

US3112192
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:08:42
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered 'Contact Made (CONTACT MADE)'	Karen Mylerberg (b) (4) (b) (4)	13 Jan 2021 22:58:45

US3112192
Folder: Safety Call OL-D8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:08:42
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	13 Jan 2021 22:58:45

US3112192
Folder: Safety Call OL-D8 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:08:42
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	13 Jan 2021 22:58:50

US3112192
Folder: Safety Call OL-D8 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:08:42
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User entered '1'	System	13 Jan 2021 22:58:50

US3112192
Folder: Safety Call OL-D8 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:08:42
OLD29 Placebo Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User entered '1'	System	13 Jan 2021 22:58:50
DataPoint set to visible.	System	13 Jan 2021 22:58:50

US3112192
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:08:42
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	03 Feb 2021 21:57:07

US3112192
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:08:42
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered '2 Feb 2021'	Natalie Moy (b) (4) (b) (4)	03 Feb 2021 21:57:07

US3112192
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:08:42
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'Clinic (Clinic)'	Natalie Moy (b) (4) (b) (4)	03 Feb 2021 21:57:07

US3112192
Folder: OL-D29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:08:42
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User entered 'OLD29'	System	03 Feb 2021 21:57:07

FDA-CBER-2022-1614-0509870

US3112192
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:08:42
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User accepted default value 'Pre-Dose (PREDOSE)'	Natalie Moy (b) (4) (b) (4)	03 Feb 2021 21:57:46

FDA-CBER-2022-1614-0509871

US3112192
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:08:42
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	03 Feb 2021 21:57:46

US3112192
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:08:42
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '2 Feb 2021'	Natalie Moy (b) (4) (b) (4)	03 Feb 2021 21:57:46

US3112192
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:08:42
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '10:14'	Natalie Moy (b) (4) (b) (4)	03 Feb 2021 21:57:46

US3112192
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:08:42
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User entered '2 Feb 2021 10:14'	System	03 Feb 2021 21:57:46

FDA-CBER-2022-1614-0509875

US3112192
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:08:42
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '98.2' F	Natalie Moy (b) (4) (b) (4)	03 Feb 2021 21:57:46

US3112192
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:08:42
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered 'Oral (Oral)'	Natalie Moy (b) (4) (b) (4)	03 Feb 2021 21:57:46

US3112192
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:08:42
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered empty.	Natalie Moy (b) (4) (b) (4)	03 Feb 2021 21:57:46

US3112192
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:08:42
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '72'	Natalie Moy (b) (4) (b) (4)	03 Feb 2021 21:57:46

US3112192
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:08:42
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User entered 'bpm'	System	03 Feb 2021 21:57:46

FDA-CBER-2022-1614-0509880

US3112192
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:08:42
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '16'	Natalie Moy (b) (4) (b) (4)	03 Feb 2021 21:57:46

FDA-CBER-2022-1614-0509881

US3112192
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:08:42
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User entered 'breaths/min'	System	03 Feb 2021 21:57:46

FDA-CBER-2022-1614-0509882

US3112192
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:08:42
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '133'	Natalie Moy (b) (4) (b) (4)	03 Feb 2021 21:57:46

FDA-CBER-2022-1614-0509883

US3112192
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:08:42
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User entered 'mmHg'	System	03 Feb 2021 21:57:46

FDA-CBER-2022-1614-0509884

US3112192
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:08:42
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '60'	Natalie Moy (b) (4) (b) (4)	03 Feb 2021 21:57:46

US3112192
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 15:08:42
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User entered 'mmHg'	System	03 Feb 2021 21:57:46

US3112192
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:08:42
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User accepted default value 'Post-Dose (POSTDOSE)'	Natalie Moy (b) (4) (b) (4)	03 Feb 2021 21:57:46

US3112192
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:08:42
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	03 Feb 2021 21:57:46

US3112192
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:08:42
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '2 Feb 2021'	Natalie Moy (b) (4) (b) (4)	03 Feb 2021 21:57:46

US3112192
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:08:42
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '10:52'	Natalie Moy (b) (4) (b) (4)	03 Feb 2021 21:57:46

US3112192
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:08:42
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User entered '2 Feb 2021 10:52'	System	03 Feb 2021 21:57:46

FDA-CBER-2022-1614-0509891

US3112192
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:08:42
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '98.9' F	Natalie Moy (b) (4) (b) (4)	03 Feb 2021 21:57:46

US3112192
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:08:42
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered 'Oral (Oral)'	Natalie Moy (b) (4) (b) (4)	03 Feb 2021 21:57:46

US3112192
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:08:42
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered empty.	Natalie Moy (b) (4) (b) (4)	03 Feb 2021 21:57:46

US3112192
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:08:42
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '78'	Natalie Moy (b) (4) (b) (4)	03 Feb 2021 21:57:46

FDA-CBER-2022-1614-0509895

US3112192
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:08:42
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User entered 'bpm'	System	03 Feb 2021 21:57:46

FDA-CBER-2022-1614-0509896

US3112192
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:08:42
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '16'	Natalie Moy (b) (4) (b) (4)	03 Feb 2021 21:57:46

US3112192
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:08:42
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User entered 'breaths/min'	System	03 Feb 2021 21:57:46

FDA-CBER-2022-1614-0509898

US3112192
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:08:42
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '138'	Natalie Moy (b) (4) (b) (4)	03 Feb 2021 21:57:46

US3112192
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:08:42
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User entered 'mmHg'	System	03 Feb 2021 21:57:46

US3112192
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:08:42
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '62'	Natalie Moy (b) (4) (b) (4)	03 Feb 2021 21:57:46

US3112192
Folder: OL-D29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 15:08:42
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User entered 'mmHg'	System	03 Feb 2021 21:57:46

US3112192
Folder: OL-D29 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 15:08:42
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	03 Feb 2021 21:57:53

US3112192
Folder: OL-D29 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 15:08:42
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered '2 Feb 2021'	Natalie Moy (b) (4) (b) (4)	03 Feb 2021 21:57:53

US3112192
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:08:42
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	03 Feb 2021 21:58:06

US3112192
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:08:42
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Natalie Moy (b) (4) (b) (4)	03 Feb 2021 21:58:06

US3112192
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:08:42

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)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Natalie Moy (b) (4) (b) (4)	03 Feb 2021 21:58:06

US3112192
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:08:42
What was the study treatment? (Unblinded)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User entered 'mRNA-1273'	System	03 Feb 2021 21:58:06
DataPoint set to visible.	System	13 Jan 2021 22:58:50

US3112192
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:08:42
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered '2 Feb 2021'	Natalie Moy (b) (4) (b) (4)	03 Feb 2021 21:58:06

US3112192
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:08:42
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered '10:21'	Natalie Moy (b) (4) (b) (4)	03 Feb 2021 21:58:06

US3112192
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:08:42
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User entered '2 Feb 2021 10:21'	System	03 Feb 2021 21:58:06

FDA-CBER-2022-1614-0509911

US3112192
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:08:42
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'Right Arm (RIGHT ARM)'	Natalie Moy (b) (4) (b) (4)	03 Feb 2021 21:58:06

US3112192
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:08:42
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User entered 'ONCE'	System	03 Feb 2021 21:58:06

US3112192
Folder: OL-D29 (1)
Form: Exposure
Generated On: 09 Jun 2021 15:08:42
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User entered 'INTRAMUSCULAR'	System	03 Feb 2021 21:58:06

US3112192
Folder: OL-D29 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:08:42
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	03 Feb 2021 21:58:20

US3112192
Folder: OL-D29 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:08:42
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User entered '1'	System	03 Feb 2021 21:58:20

US3112192
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:08:42
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	08 Mar 2021 17:25:44

US3112192
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:08:42
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '9 Feb 2021'	Brenda Grande (b) (4) (b) (4)	08 Mar 2021 17:25:44

US3112192
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:08:42
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered 'Contact Made (CONTACT MADE)'	Brenda Grande (b) (4) (b) (4)	08 Mar 2021 17:25:44

US3112192
Folder: Safety Call OL-D36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 15:08:42
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered empty.	Brenda Grande (b) (4) (b) (4)	08 Mar 2021 17:25:44

US3112192
Folder: Safety Call OL-D36 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:08:42
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	08 Mar 2021 17:25:49

US3112192
Folder: Safety Call OL-D36 (1)
Form: Continuing
Generated On: 09 Jun 2021 15:08:42
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User entered '1'	System	08 Mar 2021 17:25:49

US3112192
Folder: OL-D57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:08:42
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	10 Mar 2021 22:04:46

US3112192
Folder: OL-D57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:08:42
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '10 Mar 2021'	Brenda Grande (b) (4) (b) (4)	10 Mar 2021 22:04:46

US3112192
Folder: OL-D57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:08:42
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered 'Clinic (Clinic)'	Brenda Grande (b) (4) (b) (4)	10 Mar 2021 22:04:46

US3112192
Folder: OL-D57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 15:08:42
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User entered 'OLD57'	System	10 Mar 2021 22:04:46

FDA-CBER-2022-1614-0509926

US3112192
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	10 Mar 2021 22:05:22

US3112192
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '10 Mar 2021'	Brenda Grande (b) (4) (b) (4)	10 Mar 2021 22:05:22

US3112192
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '11:25'	Brenda Grande (b) (4) (b) (4)	10 Mar 2021 22:05:22

US3112192
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User entered '10 Mar 2021 11:25'	System	10 Mar 2021 22:05:22

US3112192
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '98.6' F	Brenda Grande (b) (4) (b) (4)	10 Mar 2021 22:05:22

US3112192
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered 'Oral (Oral)'	Brenda Grande (b) (4) (b) (4)	10 Mar 2021 22:05:22

US3112192
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered empty.	Brenda Grande (b) (4) (b) (4)	10 Mar 2021 22:05:22

US3112192
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '71'	Brenda Grande (b) (4) (b) (4)	10 Mar 2021 22:05:22

US3112192
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User entered 'bpm'	System	10 Mar 2021 22:05:22

FDA-CBER-2022-1614-0509935

US3112192
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '16'	Brenda Grande (b) (4) (b) (4)	10 Mar 2021 22:05:22

US3112192
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User entered 'breaths/min'	System	10 Mar 2021 22:05:22

FDA-CBER-2022-1614-0509937

US3112192
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '122'	Brenda Grande (b) (4) (b) (4)	10 Mar 2021 22:05:22

US3112192
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User entered 'mmHg'	System	10 Mar 2021 22:05:22

FDA-CBER-2022-1614-0509939

US3112192
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '65'	Brenda Grande (b) (4) (b) (4)	10 Mar 2021 22:05:22

US3112192
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User entered 'mmHg'	System	10 Mar 2021 22:05:22

FDA-CBER-2022-1614-0509941

US3112192
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23

FDA-CBER-2022-1614-0509942

US3112192
Folder: OL-D57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 15:08:42
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23

FDA-CBER-2022-1614-0509943

US3112192
Folder: OL-D57 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 15:08:42
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	10 Mar 2021 22:05:40

US3112192
Folder: OL-D57 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 15:08:42
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '10 Mar 2021'	Brenda Grande (b) (4) (b) (4)	10 Mar 2021 22:05:40

FDA-CBER-2022-1614-0509945

US3112192
Folder: OL-D57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:08:42
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	10 Mar 2021 22:05:51

US3112192
Folder: OL-D57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:08:42
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '10 Mar 2021'	Brenda Grande (b) (4) (b) (4)	10 Mar 2021 22:05:51

US3112192
Folder: OL-D57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:08:42
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '11:35'	Brenda Grande (b) (4) (b) (4)	10 Mar 2021 22:05:51

US3112192
Folder: OL-D57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 15:08:42
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:08:23
User entered '10 Mar 2021 11:35'	System	10 Mar 2021 22:05:51

FDA-CBER-2022-1614-0509949

US3112192
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 09 Jun 2021 15:08:42
Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:44:57
User closed query 'Per DM CLR: Medical Attention was checked for DAY 8-19 on Diary Dose 2. However, there is no Solicited Adverse Reaction (recorded as AE) with "Was this a medically-attended AE?" = YES. Please review and ensure that this Solicited Adverse reaction is captured as an Adverse event and response to "Was this a medically-attended AE?" is YES. Review and update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 04:39:01
Query 'Per DM CLR: Medical Attention was checked for DAY 8-19 on Diary Dose 2. However, there is no Solicited Adverse Reaction (recorded as AE) with "Was this a medically-attended AE?" = YES. Please review and ensure that this Solicited Adverse reaction is captured as an Adverse event and response to "Was this a medically-attended AE?" is YES. Review and update eCRF as appropriate. ' answered with 'Please note that eDiary survey question is posited as follows "Did you receive ANY medical attention (doctor visit, other) for ANY illness or symptoms?" Patient reported receipt of medical attention pertaining to other already reported adverse events unrelated to vaccine or study procedures. Please see MAAE terms; "Left Shoulder Contusion" and "Left Knee contusion" as pertaining to a mechanical fall that the subject experienced and saw a HCP for. ' (Site from DM).	Matthew Musikanth (b) (4)	20 Apr 2021 20:20:08
User opened query 'Per DM CLR: Medical Attention was checked for DAY 8-19 on Diary Dose 2. However, there is no Solicited Adverse Reaction (recorded as AE) with "Was this a medically-attended AE?" = YES. Please review and ensure that this Solicited Adverse reaction is captured as an Adverse event and response to "Was this a medically-attended AE?" is YES. Review and update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 22:32:49

FDA-CBER-2022-1614-0509950

US3112192
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 09 Jun 2021 15:08:42
Did the participant experience any adverse events?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User closed query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of JOINT ACHES persist beyond Day 7 (start date: Day 1; end date: Day 21). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 13:12:16
User closed query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of MUSCLE ACHES persist beyond Day 7 (start date: Day 1; end date: Day 21). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 13:12:14
User closed query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 1; end date: Day 19). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 13:12:10
Query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of MUSCLE ACHES persist beyond Day 7 (start date: Day 1; end date: Day 21). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' answered with 'updated' (Site from DM).	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:26:13
Query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 1; end date: Day 19). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' answered with 'updated' (Site from DM).	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:26:08

US3112192
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 09 Jun 2021 15:08:42
Did the participant experience any adverse events?

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of JOINT ACHES persist beyond Day 7 (start date: Day 1; end date: Day 21). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' answered with 'updated ' (Site from DM).	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:26:04
User opened query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of MUSCLE ACHES persist beyond Day 7 (start date: Day 1; end date: Day 21). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	06 Feb 2021 11:50:27
User opened query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of JOINT ACHES persist beyond Day 7 (start date: Day 1; end date: Day 21). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	06 Feb 2021 11:50:20
User opened query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 1; end date: Day 19). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	06 Feb 2021 11:50:13
User entered 'Yes (Y)'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:08:12

US3112192
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:08:42
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:29

US3112192
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:08:42
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Skin injuries NEC, PT: Contusion, LLT: Contusion of knee - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Dec 2020 21:56:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Dec 2020 21:56:29
Data point term sent to Coder	System	31 Dec 2020 21:55:16
Coding entries removed.	Brenda Grande (b) (4) (b) (4)	31 Dec 2020 21:54:40
User entered 'LEFT KNEE CONTUSION' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	31 Dec 2020 21:54:40
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Skin injuries NEC, PT: Contusion, LLT: Contusion of knee - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 19:41:23
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 19:41:23
Data point term sent to Coder	System	23 Nov 2020 20:29:18
Coding entries removed.	Natalie Moy (b) (4) (b) (4)	23 Nov 2020 20:28:21
User entered 'LEFT KNEE CONTUSION secondary to mechanical fall' reason for change: Data Entry Error	Natalie Moy (b) (4) (b) (4)	23 Nov 2020 20:28:21
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Skin injuries NEC, PT: Contusion, LLT: Contusion of knee - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 05:52:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 05:52:24
Data point term sent to Coder	System	13 Oct 2020 16:58:38
User closed query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. Example: 1) LEFT KNEE CONTUSIOIN 2) MECHANICAL FALL' (Site from System).	System	13 Oct 2020 16:58:34

US3112192
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:08:42
Adverse event

Audit	User	Time (GMT)
Query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. Example: 1) LEFT KNEE CONTUSIOIN 2) MECHANICAL FALL' answered with 'updated' (Site from System).	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 16:58:34
User entered 'LEFT KNEE CONTUSION' reason for change: Data Entry Error	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 16:58:29
User opened query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. Example: 1) LEFT KNEE CONTUSIOIN 2) MECHANICAL FALL' (Site from System).	Coder Import (b) (4) (b) (4)	08 Oct 2020 14:14:19
Data point term sent to Coder	System	18 Sep 2020 19:09:54
User entered 'left knee contusion secondary to mechanical fall'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:09:48

US3112192
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:08:42
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered 'Yes (Y)'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:09:48

US3112192
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:08:42
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered 'No (N)'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:09:48

US3112192
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:08:42
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered 'No (N)'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:09:48

US3112192
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:08:42
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered '1 Sep 2020'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:09:48

US3112192
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:08:42
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
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	18 Sep 2020 19:10:12
User entered empty; reason for change Data Entry Error	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:10:12
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	18 Sep 2020 19:09:48
User entered '20:30'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:09:48

US3112192
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:08:42
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:29
User entered empty.	System	18 Sep 2020 19:10:12
User entered '1 Sep 2020 20:30'	System	18 Sep 2020 19:09:48

US3112192
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:08:42
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
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).	(b) (4), (b) (6)	07 Dec 2020 17:30:14
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 'updated' (Site from DM).	Matthew Musikanth (b) (4)	03 Dec 2020 00:55:39
User entered 'No (N)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	03 Dec 2020 00:55:32
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)	25 Nov 2020 04:55:49
User entered 'Yes (Y)'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:09:48

US3112192
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:08:42
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered '16 Sep 2020' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	03 Dec 2020 00:55:32
User entered empty.	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:09:48

US3112192
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:08:42
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered empty.	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:09:48

US3112192
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:08:42
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:29
User entered empty.	System	18 Sep 2020 19:09:48

FDA-CBER-2022-1614-0509965

US3112192
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:08:42
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:09:48

US3112192
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:08:42
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered 'No (N)'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:09:48

US3112192
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:08:42
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered '0'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:09:48

US3112192
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:08:42
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered '0'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:09:48

US3112192
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:08:42
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered '0'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:09:48

US3112192
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:08:42
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered empty.	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:09:48

US3112192
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:08:42
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered empty.	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:09:48

US3112192
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:08:42
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered empty.	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:09:48

US3112192
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:08:42
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered empty.	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:09:48

US3112192
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:08:42
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered '0'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:09:48

US3112192
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:08:42
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered '0'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:09:48

US3112192
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:08:42
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered '0'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:09:48

US3112192
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:08:42
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered 'Not Related (NOT RELATED)'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:09:48

US3112192
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:08:42
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered 'Not Related (NOT RELATED)'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:09:48

US3112192
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:08:42
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered 'None (NONE)'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:09:48

US3112192
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:08:42
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered '0'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:09:48

US3112192
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:08:42
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered '1'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:09:48

US3112192
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:08:42
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered '0'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:09:48

US3112192
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:08:42
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	03 Dec 2020 00:55:32
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:09:48

US3112192
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:08:42
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered empty.	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:09:48

US3112192
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:08:42
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:29
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered empty.	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:09:48

US3112192
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:08:42
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:29
User entered '0'	System	18 Sep 2020 19:09:48

US3112192
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:08:42
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:29
User entered '1'	System	18 Sep 2020 19:09:48

US3112192
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 15:08:42
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:29

FDA-CBER-2022-1614-0509989

US3112192
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:08:42
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:34

FDA-CBER-2022-1614-0509990

US3112192
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:08:42
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:34
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User closed query 'Requery: Coding guidelines require the injury be split from the event of FALL. ' (Site from Coder).	(b) (4), (b) (6)	06 Jan 2021 00:14:13
Query 'Requery: Coding guidelines require the injury be split from the event of FALL. ' answered with 'per PI fall is not an AE will update AE accordingly ' (Site from Coder).	Brenda Grande (b) (4) (b) (4)	31 Dec 2020 21:55:55
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Skin injuries NEC, PT: Contusion, LLT: Contusion of shoulder region - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Dec 2020 21:55:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Dec 2020 21:55:20
Data point term sent to Coder	System	31 Dec 2020 21:54:16
Coding entries removed.	Brenda Grande (b) (4) (b) (4)	31 Dec 2020 21:54:04
User entered 'LEFT SHOULDER CONTUSION' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	31 Dec 2020 21:54:04
User opened query 'Requery: Coding guidelines require the injury be split from the event of FALL. ' (Site from Coder).	(b) (4), (b) (6)	26 Dec 2020 15:20:13
User closed query 'For coding purposes, please split LEFT SHOULDER CONTUSION SECONDARY TO MECHANICAL FALL into separate entries. 1. LEFT SHOULDER CONTUSION [SECONDARY TO MECHANICAL FALL] and 2. MECHANICAL FALL' (Site from Coder).	(b) (4), (b) (6)	26 Dec 2020 15:20:13
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Skin injuries NEC, PT: Contusion, LLT: Contusion of shoulder region - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Dec 2020 20:20:23
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Dec 2020 20:20:23

US3112192
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:08:42
Adverse event

Audit	User	Time (GMT)
Query 'For coding purposes, please split LEFT SHOULDER CONTUSION SECONDARY TO MECHANICAL FALL into separate entries. 1. LEFT SHOULDER CONTUSION [SECONDARY TO MECHANICAL FALL] and 2. MECHANICAL FALL' answered with 'Updated, Mechanical fall not to be captured as AE per PI' (Site from Coder).	Matthew Musikanth (b) (4)	10 Dec 2020 16:34:53
User opened query 'For coding purposes, please split LEFT SHOULDER CONTUSION SECONDARY TO MECHANICAL FALL into separate entries. 1. LEFT SHOULDER CONTUSION [SECONDARY TO MECHANICAL FALL] and 2. MECHANICAL FALL' (Site from Coder).	(b) (4), (b) (6)	10 Dec 2020 12:45:24
User closed query 'For coding purposes, please split LEFT SHOULDER CONTUSION SECONDARY TO MECHANICAL FALL into separate entries. 1. LEFT SHOULDER CONTUSION [SECONDARY TO MECHANICAL FALL] and 2. MECHANICAL FALL' (Site from Coder).	(b) (4), (b) (6)	10 Dec 2020 12:45:24
Data point term sent to Coder	System	03 Dec 2020 00:57:32
Query 'For coding purposes, please split LEFT SHOULDER CONTUSION SECONDARY TO MECHANICAL FALL into separate entries. 1. LEFT SHOULDER CONTUSION [SECONDARY TO MECHANICAL FALL] and 2. MECHANICAL FALL' answered with 'updated' (Site from Coder).	Matthew Musikanth (b) (4)	03 Dec 2020 00:56:57
Coding entries removed.	Matthew Musikanth (b) (4)	03 Dec 2020 00:56:48
User entered 'LEFT SHOULDER CONTUSION [SECONDARY TO MECHANICAL FALL]' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	03 Dec 2020 00:56:48
User opened query 'For coding purposes, please split LEFT SHOULDER CONTUSION SECONDARY TO MECHANICAL FALL into separate entries. 1. LEFT SHOULDER CONTUSION [SECONDARY TO MECHANICAL FALL] and 2. MECHANICAL FALL' (Site from Coder).	(b) (4), (b) (6)	29 Nov 2020 15:29:37
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Skin injuries NEC, PT: Contusion, LLT: Contusion of shoulder region - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 19:41:23

US3112192
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:08:42
Adverse event

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 19:41:23
Data point term sent to Coder	System	23 Nov 2020 20:28:17
Coding entries removed.	Natalie Moy (b) (4) (b) (4)	23 Nov 2020 20:28:09
User entered 'LEFT SHOULDER CONTUSION Secondary to mechanical fall' reason for change: Data Entry Error	Natalie Moy (b) (4) (b) (4)	23 Nov 2020 20:28:09
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Skin injuries NEC, PT: Contusion, LLT: Contusion of shoulder region - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 05:50:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 05:50:50
Data point term sent to Coder	System	13 Oct 2020 16:59:39
User closed query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. Example: 1) LEFT SHOULDER CONTUSION 2) MECHANICAL FALL' (Site from System).	System	13 Oct 2020 16:58:50
Query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. Example: 1) LEFT SHOULDER CONTUSION 2) MECHANICAL FALL' answered with 'updated' (Site from System).	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 16:58:50
User entered 'LEFT SHOULDER CONTUSION' reason for change: Data Entry Error	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 16:58:43
User opened query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. Example: 1) LEFT SHOULDER CONTUSION 2) MECHANICAL FALL' (Site from System).	Coder Import (b) (4) (b) (4)	08 Oct 2020 14:28:20
Data point term sent to Coder	System	18 Sep 2020 19:11:56
User entered 'left shoulder contusion secondary to mechanical fall'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:11:18

FDA-CBER-2022-1614-0509993

US3112192
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:08:42
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:34
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered 'Yes (Y)'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:11:18

US3112192
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:08:42
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:34
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered 'No (N)'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:11:18

US3112192
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:08:42
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:34
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered 'No (N)'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:11:18

US3112192
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:08:42
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:34
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered '1 Sep 2020'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:11:18

US3112192
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:08:42
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:34
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered empty.	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:11:18

US3112192
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:08:42
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:34
User entered empty.	System	18 Sep 2020 19:11:18

US3112192
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:08:42
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:34
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
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).	(b) (4), (b) (6)	07 Dec 2020 17:30:39
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 'updated' (Site from DM).	Matthew Musikanth (b) (4)	03 Dec 2020 00:55:05
User entered 'No (N)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	03 Dec 2020 00:54:51
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)	25 Nov 2020 04:55:58
User entered 'Yes (Y)'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:11:18

US3112192
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:08:42
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:34
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered '21 Sep 2020' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	03 Dec 2020 00:54:51
User entered empty.	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:11:18

US3112192
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:08:42
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:34
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered empty.	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:11:18

US3112192
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:08:42
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:34
User entered empty.	System	18 Sep 2020 19:11:18

US3112192
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:08:42
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:34
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:11:18

US3112192
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:08:42
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:34
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered 'No (N)'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:11:18

US3112192
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:08:42
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:34
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered '0'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:11:18

US3112192
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:08:42
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:34
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered '0'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:11:18

US3112192
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:08:42
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:34
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered '0'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:11:18

US3112192
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:08:42
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:34
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered empty.	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:11:18

US3112192
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:08:42
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:34
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered empty.	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:11:18

US3112192
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:08:42
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:34
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered empty.	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:11:18

US3112192
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:08:42
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:34
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered empty.	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:11:18

US3112192
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:08:42
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:34
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered '0'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:11:18

US3112192
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:08:42
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:34
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered '0'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:11:18

US3112192
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:08:42
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:34
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered '0'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:11:18

US3112192
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:08:42
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:34
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered 'Not Related (NOT RELATED)'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:11:18

US3112192
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:08:42
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:34
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered 'Not Related (NOT RELATED)'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:11:18

US3112192
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:08:42
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:34
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered 'None (NONE)'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:11:18

US3112192
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:08:42
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:34
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered '0'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:11:18

US3112192
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:08:42
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:34
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered '1'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:11:18

US3112192
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:08:42
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:34
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User closed query 'Per DM CLR - RQ: Site's response noted. However, the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 02:59:50
Query 'Per DM CLR - RQ: Site's response noted. However, the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' answered with 'has been updated ' (Site from DM).	Brenda Grande (b) (4) (b) (4)	15 Jan 2021 00:08:18
User entered '0' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	14 Jan 2021 23:55:12
User opened query 'Per DM CLR - RQ: Site's response noted. However, the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 23:45:03
User closed query 'Per DM CLR: RQ: Response noted, however, MRI is just a diagnostic procedure and not therapeutic. Please update response or record any therapeutic procedure done if available. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 08:29:51
Query 'Per DM CLR: RQ: Response noted, however, MRI is just a diagnostic procedure and not therapeutic. Please update response or record any therapeutic procedure done if available. Otherwise, clarify.' answered with 'MRI added to concomitant procedure page ' (Site from DM).	Brenda Grande (b) (4) (b) (4)	10 Dec 2020 00:00:19
User opened query 'Per DM CLR: RQ: Response noted, however, MRI is just a diagnostic procedure and not therapeutic. Please update response or record any therapeutic procedure done if available. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 12:29:09

US3112192
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:08:42
Concomitant Procedure

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 10:42:50
Query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'please see left shoulder mri in con procedure. ' (Site from DM).	Matthew Musikanth (b) (4)	04 Nov 2020 22:05:52
User opened query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 09:47:54
User entered '1'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:11:18

US3112192
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:08:42
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:34
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	03 Dec 2020 00:54:51
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:11:18

US3112192
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:08:42
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:34
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered empty.	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:11:18

US3112192
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:08:42
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:34
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered empty.	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:11:18

US3112192
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:08:42
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:34
User entered '0'	System	18 Sep 2020 19:11:18

US3112192
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:08:42
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:34
User entered '1'	System	18 Sep 2020 19:11:18

US3112192
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 15:08:42
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:57:34

FDA-CBER-2022-1614-0510028

US3112192
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:08:42
AEID

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:28
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:43
User entered 'USA-US062-2020-mRNA-1273-P301000006'	System	23 Oct 2020 21:14:34
User entered 'New'	(b) (4), (b) (6)	23 Oct 2020 21:14:34

US3112192
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:08:42
Adverse event

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User closed query 'Per DM CLR: Please confirm if this AE is a worsening of ATRIAL FIBRILLATION noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure any Con Med indications are updated if required. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 12:16:05
Query 'Per DM CLR: Please confirm if this AE is a worsening of ATRIAL FIBRILLATION noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure any Con Med indications are updated if required. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria. ' answered with 'not worsening, just an episode of condition' (Site from DM).	Natalie Moy (b) (4) (b) (4)	23 Nov 2020 22:24:08
User opened query 'Per DM CLR: Please confirm if this AE is a worsening of ATRIAL FIBRILLATION noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure any Con Med indications are updated if required. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	21 Nov 2020 09:24:06
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 23:34:19
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Paroxysmal atrial fibrillation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 23:05:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 23:05:24
Data point term sent to Coder	System	05 Nov 2020 23:04:02
DataPoint Un-verified.	Matthew Musikanth (b) (4)	05 Nov 2020 23:03:33
Coding entries removed.	Matthew Musikanth (b) (4)	05 Nov 2020 23:03:33

US3112192
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:08:42
Adverse event

Audit	User	Time (GMT)
User entered 'Paroxysmal ATRIAL FIBRILLATION' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	05 Nov 2020 23:03:33
User closed query 'PV Query: Atrial fibrillation was noted in the subject's medical history with a start date of APR-2020 and continuing. Was this event of atrial fibrillation (with onset date of 18 Oct 2020) a worsening of the of the subject's medical history of atrial fibrillation? Please provide clarification.' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 19:57:41
Query 'PV Query: Atrial fibrillation was noted in the subject's medical history with a start date of APR-2020 and continuing. Was this event of atrial fibrillation (with onset date of 18 Oct 2020) a worsening of the of the subject's medical history of atrial fibrillation? Please provide clarification.' answered with 'No, separate event. These were two separate episodes of atrial fibrillation. ' (Site from Safety).	Matthew Musikanth (b) (4)	02 Nov 2020 23:40:54
User opened query 'PV Query: Atrial fibrillation was noted in the subject's medical history with a start date of APR-2020 and continuing. Was this event of atrial fibrillation (with onset date of 18 Oct 2020) a worsening of the of the subject's medical history of atrial fibrillation? Please provide clarification.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 21:03:57
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:43:21
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 23:43:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 23:43:28
Data point term sent to Coder	System	22 Oct 2020 23:42:52
User entered 'Atrial Fibrillation'	Matthew Musikanth (b) (4)	22 Oct 2020 23:42:13

US3112192
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:08:42
Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:43:28
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	22 Oct 2020 23:42:13

US3112192
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:08:42
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:43:30
User entered 'No (N)'	Matthew Musikanth (b) (4)	22 Oct 2020 23:42:13

US3112192
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:08:42
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:43:32
User entered 'No (N)'	Matthew Musikanth (b) (4)	22 Oct 2020 23:42:13

US3112192
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:08:42
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:25:34
DataPoint Un-verified.	Matthew Musikanth (b) (4)	18 Nov 2020 21:19:08
User entered '17 Oct 2020' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	18 Nov 2020 21:19:08
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:43:36
User entered '18 Oct 2020'	Matthew Musikanth (b) (4)	22 Oct 2020 23:42:13

US3112192
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:08:42
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:45:51
User entered empty.	Matthew Musikanth (b) (4)	22 Oct 2020 23:42:13

US3112192
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:08:42
AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 23:42:13

US3112192
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:08:42
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:45:53
User entered 'No (N)'	Matthew Musikanth (b) (4)	22 Oct 2020 23:42:13

US3112192
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:08:42
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:45:55
User entered '20 Oct 2020'	Matthew Musikanth (b) (4)	22 Oct 2020 23:42:13

US3112192
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:08:42
End time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:45:58
User entered empty.	Matthew Musikanth (b) (4)	22 Oct 2020 23:42:13

US3112192
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:08:42
AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 23:42:13

US3112192
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:08:42
Severity

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 23:34:38
User closed query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 19:57:49
Query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' answered with 'updated' (Site from Safety).	Matthew Musikanth (b) (4)	02 Nov 2020 23:43:00
DataPoint Un-verified.	Matthew Musikanth (b) (4)	02 Nov 2020 23:42:54
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	02 Nov 2020 23:42:54
User opened query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 21:04:38
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:45:59
User entered 'Grade 3/Severe (Grade 3/Severe)'	Matthew Musikanth (b) (4)	22 Oct 2020 23:42:13

US3112192
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:08:42
Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:46:09
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	22 Oct 2020 23:42:13

US3112192
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:08:42
Death

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:46:13
User entered '0'	Matthew Musikanth (b) (4)	22 Oct 2020 23:42:13

US3112192
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:08:42
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:46:15
User entered '0'	Matthew Musikanth (b) (4)	22 Oct 2020 23:42:13

US3112192
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:08:42
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:46:17
User entered '1'	Matthew Musikanth (b) (4)	22 Oct 2020 23:42:13

US3112192
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:08:42
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:25:40
DataPoint Un-verified.	Matthew Musikanth (b) (4)	18 Nov 2020 21:19:08
User entered '17 Oct 2020' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	18 Nov 2020 21:19:08
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:46:19
User entered '18 Oct 2020'	Matthew Musikanth (b) (4)	22 Oct 2020 23:42:13

US3112192
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:08:42
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:46:21
User entered '20 Oct 2020'	Matthew Musikanth (b) (4)	22 Oct 2020 23:42:13

US3112192
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:08:42
Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:53:39
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	22 Oct 2020 23:42:34
Query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).	System	22 Oct 2020 23:42:34
User entered 'No (N)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	22 Oct 2020 23:42:34
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	22 Oct 2020 23:42:13
User entered 'Unknown (UNK)'	Matthew Musikanth (b) (4)	22 Oct 2020 23:42:13

US3112192
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:08:42
Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:53:41
User entered empty.	Matthew Musikanth (b) (4)	22 Oct 2020 23:42:13

US3112192
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:08:42
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:53:43
User entered '0'	Matthew Musikanth (b) (4)	22 Oct 2020 23:42:13

US3112192
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:08:42
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:53:44
User entered '0'	Matthew Musikanth (b) (4)	22 Oct 2020 23:42:13

US3112192
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:08:42
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:53:46
User entered '0'	Matthew Musikanth (b) (4)	22 Oct 2020 23:42:13

US3112192
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:08:42
Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:53:55
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	22 Oct 2020 23:42:13

US3112192
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:08:42
Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:53:57
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth (b) (4)	22 Oct 2020 23:42:13

US3112192
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:08:42
Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 23:34:52
User closed query 'PV Query: As the last dose of study drug was given on 11 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 19:57:53
Query 'PV Query: As the last dose of study drug was given on 11 Sep 2020, please update the action taken with study drug from none to not applicable.' answered with 'updated' (Site from Safety).	Matthew Musikanth (b) (4)	02 Nov 2020 23:43:06
DataPoint Un-verified.	Matthew Musikanth (b) (4)	02 Nov 2020 23:41:19
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	02 Nov 2020 23:41:19
User opened query 'PV Query: As the last dose of study drug was given on 11 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 21:04:49
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:53:59
User entered 'None (NONE)'	Matthew Musikanth (b) (4)	22 Oct 2020 23:42:13

US3112192
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:08:42
None

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	05 Nov 2020 19:02:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:12
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	22 Oct 2020 23:42:13
User entered '0'	Matthew Musikanth (b) (4)	22 Oct 2020 23:42:13

US3112192
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:08:42
Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 23:34:57
DataPoint Un-verified.	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:02:39
User entered '1' reason for change: Data Entry Error	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:02:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:13
User entered '0'	Matthew Musikanth (b) (4)	22 Oct 2020 23:42:13

US3112192
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:08:42
Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:15
User entered '0'	Matthew Musikanth (b) (4)	22 Oct 2020 23:42:13

US3112192
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:08:42
Outcome

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:18
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Matthew Musikanth (b) (4)	22 Oct 2020 23:42:13

US3112192
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:08:42
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:22
User entered empty.	Matthew Musikanth (b) (4)	22 Oct 2020 23:42:13

US3112192
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:08:42
Narrative

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User closed query 'Per DM CLR: SAE Narrative = BLOOD WORK. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 03:00:34
Query 'Per DM CLR: SAE Narrative = BLOOD WORK. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'blood work is diagnostic procedure not conproc ' (Site from DM).	Brenda Grande (b) (4) (b) (4)	15 Jan 2021 00:24:56
User opened query 'Per DM CLR: SAE Narrative = BLOOD WORK. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 23:48:25
User closed query 'Per DM CLR: Narrative suggests that subject had CXR & ECG. However, these are not recorded in the Concomitant Procedure eCRF. Review and record as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 03:31:49
Query 'Per DM CLR: Narrative suggests that subject had CXR & ECG. However, these are not recorded in the Concomitant Procedure eCRF. Review and record as appropriate. Otherwise, clarify. ' answered with 'CXR and ECG have been added to concomitant procedures ' (Site from DM).	Brenda Grande (b) (4) (b) (4)	10 Dec 2020 22:03:52
User opened query 'Per DM CLR: Narrative suggests that subject had CXR & ECG. However, these are not recorded in the Concomitant Procedure eCRF. Review and record as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 12:29:35
User closed query 'PV Query: Please provide the dates for diagnostic test results for ECG and CXR ' (Site from Safety).	(b) (4), (b) (6)	03 Dec 2020 12:47:28

US3112192
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:08:42
Narrative

Audit	User	Time (GMT)
Query 'PV Query: Please provide the dates for diagnostic test results for ECG and CXR ' answered with 'CXR - 17Oct2020 ; no radiographic evidence of an acute cardiopulmonary process. ECG - 17Oct2020 ; Normal sinus rhythm. Possible left atrial enlargement. right bundle branch blockage. Abnormal ECG, no significant change found. ' (Site from Safety).	Matthew Musikanth (b) (4)	02 Dec 2020 00:51:59
User opened query 'PV Query: Please provide the dates for diagnostic test results for ECG and CXR ' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 19:46:02
User closed query 'PV Query: Please provide the dates, units and reference ranges for reported laboratory and diagnostic test results for "blood work unremarkable, troponin HS 5.9, hyperchloremia 110. NO significant change found in ECG. CXR reviewed and no active disease shown".' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 13:14:09
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 21:26:42
Query 'PV Query: Please provide the dates, units and reference ranges for reported laboratory and diagnostic test results for "blood work unremarkable, troponin HS 5.9, hyperchloremia 110. NO significant change found in ECG. CXR reviewed and no active disease shown".' answered with 'Please note for relevant blood work; Troponin-HS 5.9 pg/ml - 17Oct2020 1651, 7.4 pg/ml - 17Oct2020 2239, 7.1 pg/ml- 18Oct2020 Reference range [0.0-14.9 pg/ml] Chloride 110 mol/L - 17Oct2020, 112 mmol/L - 18 Oct2020, 101 mmol/L - 19Oct2020, 102 mmol/L - 20 Oct2020 Reference Range [98-108- mmol/L] ' (Site from Safety).	Matthew Musikanth (b) (4)	18 Nov 2020 21:19:20
DataPoint Un-verified.	Matthew Musikanth (b) (4)	18 Nov 2020 21:19:08

FDA-CBER-2022-1614-0510063

US3112192
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:08:42
Narrative

Audit	User	Time (GMT)
User entered 'PATIENT REPORTS HAVING TAKEN BLOOD PRESSURE AT HOME AND HAVING HIGH READING IN EXCESS OF 195 SYSTOLIC. CALLED HOSPITAL AND WAS ADVISED TO PRESENT FOR ATRIAL FIBRILLATION. PATIENT ADMITTED ON 17OCT2020 AND DISCHARGED ON 20OCT2020. blood work unremarkable, troponin HS 5.9, hyperchloremia 110. NO significant change found in ECG. CXR reviewed and no active disease shown. Diagnosis of Paroxysmal atrial fibrillation assessed.' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	18 Nov 2020 21:19:08
User closed query 'PV Query: Please confirm if ALLERGIES is considered medical history (prior to start of study); since it is reported as the indication for concomitant medications MONTELUKAST, CLARITIN and FLUTICAZONE. If considered MH, please add to MH eCRF' (Site from Safety).	(b) (4), (b) (6)	18 Nov 2020 18:15:13
User closed query 'PV Query: Please provide the start dates for concomitant medications MONTELUKAST, CLARITIN and FLUTICAZONE.' (Site from Safety).	(b) (4), (b) (6)	18 Nov 2020 18:15:05
Query 'PV Query: Please confirm if ALLERGIES is considered medical history (prior to start of study); since it is reported as the indication for concomitant medications MONTELUKAST, CLARITIN and FLUTICAZONE. If considered MH, please add to MH eCRF' answered with 'montelukast is for asthma. seasonal allergies has been updated to med hx ' (Site from Safety).	Natalie Moy (b) (4) (b) (4)	17 Nov 2020 21:22:57
Query 'PV Query: Please provide the start dates for concomitant medications MONTELUKAST, CLARITIN and FLUTICAZONE.' answered with 'pt was contacted, uncertain about the start dates for montelukast, fluticazone, and claritin. has been taking these medications for years' (Site from Safety).	Natalie Moy (b) (4) (b) (4)	17 Nov 2020 21:21:46
User opened query 'PV Query: Please provide the dates, units and reference ranges for reported laboratory and diagnostic test results for "blood work unremarkable, troponin HS 5.9, hyperchloremia 110. NO significant change found in ECG. CXR reviewed and no active disease shown".' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 22:13:27

US3112192
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:08:42
Narrative

Audit	User	Time (GMT)
User opened query 'PV Query: Please confirm if ALLERGIES is considered medical history (prior to start of study); since it is reported as the indication for concomitant medications MONTELUKAST, CLARITIN and FLUTICAZONE. If considered MH, please add to MH eCRF' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 22:08:16
User opened query 'PV Query: Please provide the start dates for concomitant medications MONTELUKAST, CLARITIN and FLUTICAZONE.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 22:04:55
User closed query 'PV Query: Please clarify if the subject's blood pressure of 195 systolic is consistent with the subject's baseline BP readings. If not, please consider reporting AE/SAE Worsening blood pressure.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 13:15:55
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 13:15:51
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 13:15:48
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 13:15:45
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Concomitant Medication taken, see conmed log for aspirin. ' (Site from Safety).	Matthew Musikanth (b) (4)	05 Nov 2020 23:15:23

FDA-CBER-2022-1614-0510065

US3112192
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:08:42
Narrative

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Blood work unremarkable, troponin HS 5.9, hyperchloremia 110. NO significant change found in ECG. CXR reviewed and no active disease shown. ' (Site from Safety).	Matthew Musikanth (b) (4)	05 Nov 2020 23:06:47
Query 'PV Query: Please clarify if the subject's blood pressure of 195 systolic is consistent with the subject's baseline BP readings. If not, please consider reporting AE/SAE Worsening blood pressure.' answered with 'BP at admission 168/81, AE definition paroxysmal atrial fibrillation per medical records. ' (Site from Safety).	Matthew Musikanth (b) (4)	05 Nov 2020 23:03:15
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'COVID-19 Mol Amp - 17Oct2020 - Not detected' (Site from Safety).	Matthew Musikanth (b) (4)	05 Nov 2020 23:00:21
User opened query 'PV Query: Please clarify if the subject's blood pressure of 195 systolic is consistent with the subject's baseline BP readings. If not, please consider reporting AE/SAE Worsening blood pressure.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 21:05:29
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 21:04:27
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 21:04:19
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 21:04:12

US3112192
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:08:42
Narrative

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:23
User entered 'Patient reports having taken blood pressure at home and having high reading in excess of 195 systolic. Called hospital and was advised to present for atrial fibrillation. Patient admitted on 18oct2020 and discharged on 20oct2020. Patient un able to recall specific procedures or medications, will request medical records for further clarification. Will update.'	Matthew Musikanth (b) (4)	22 Oct 2020 23:42:13

US3112192
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:08:42
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 23:42:13

US3112192
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:08:42
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 23:42:13

US3112192
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 15:08:42
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	22 Oct 2020 23:42:13

US3112192
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:08:42
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:02

FDA-CBER-2022-1614-0510071

US3112192
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:08:42
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Muscle ache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Feb 2021 23:28:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Feb 2021 23:28:41
Data point term sent to Coder	System	09 Feb 2021 23:27:55
User entered 'muscle ache'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:27:05

US3112192
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:08:42
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered 'No (N)'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:27:05

US3112192
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:08:42
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:27:05

US3112192
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:08:42
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered 'No (N)'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:27:05

US3112192
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:08:42
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered '11 Sep 2020'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:27:05

US3112192
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:08:42
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	23 Feb 2021 00:06:39
Query 'Data is required. Please provide.' answered with 'time is unknown ' (Site from System).	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:27:10
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Feb 2021 23:27:05
User entered empty.	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:27:05

US3112192
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:08:42
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:02
User entered empty.	System	09 Feb 2021 23:27:05

US3112192
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:08:42
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered 'No (N)'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:27:05

US3112192
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:08:42
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered '01 Oct 2020'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:27:05

US3112192
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:08:42
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	23 Feb 2021 00:06:42
Query 'Data is required. Please provide.' answered with 'time is unknown ' (Site from System).	(b) (4), (b) (6)	09 Feb 2021 23:27:13
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Feb 2021 23:27:05
User entered empty.	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:27:05

US3112192
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:08:42
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:02
User entered empty.	System	09 Feb 2021 23:27:05

US3112192
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:08:42
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered 'Grade 1/Mild (Grade 1/Mild)'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:27:05

US3112192
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:08:42
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered 'No (N)'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:27:05

US3112192
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:08:42
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered '0'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:27:05

US3112192
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:08:42
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered '0'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:27:05

US3112192
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:08:42
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered '0'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:27:05

US3112192
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:08:42
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered empty.	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:27:05

US3112192
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:08:42
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered empty.	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:27:05

US3112192
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:08:42
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered empty.	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:27:05

US3112192
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:08:42
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered empty.	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:27:05

US3112192
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:08:42
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered '0'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:27:05

US3112192
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:08:42
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered '0'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:27:05

US3112192
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:08:42
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered '0'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:27:05

US3112192
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:08:42
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered 'Related (RELATED)'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:27:05

US3112192
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:08:42
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered 'Not Related (NOT RELATED)'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:27:05

US3112192
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:08:42
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered 'None (NONE)'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:27:05

US3112192
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:08:42
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered '1'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:27:05

US3112192
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:08:42
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered '0'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:27:05

US3112192
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:08:42
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered '0'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:27:05

US3112192
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:08:42
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:27:05

US3112192
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:08:42
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered empty.	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:27:05

US3112192
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:08:42
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered empty.	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:27:05

US3112192
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:08:42
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:02
User entered '0'	System	09 Feb 2021 23:27:05

US3112192
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:08:42
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:02
User entered '0'	System	09 Feb 2021 23:27:05

US3112192
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 09 Jun 2021 15:08:42
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:02

FDA-CBER-2022-1614-0510106

US3112192
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 15:08:42
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:04

FDA-CBER-2022-1614-0510107

US3112192
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 15:08:42
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:04
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User closed query 'Per DM CLR: Please review AE and please update to specify the location of Joint Aches. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 05:39:13
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Generalized joint pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Mar 2021 16:00:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Mar 2021 16:00:43
Data point term sent to Coder	System	02 Mar 2021 15:59:37
Query 'Per DM CLR: Please review AE and please update to specify the location of Joint Aches. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' answered with 'updated' (Site from DM).	Brenda Grande (b) (4) (b) (4)	02 Mar 2021 15:58:49
Coding entries removed.	Brenda Grande (b) (4) (b) (4)	02 Mar 2021 15:58:44
User entered 'general JOINT ACHES' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	02 Mar 2021 15:58:44
User opened query 'Per DM CLR: Please review AE and please update to specify the location of Joint Aches. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 11:22:25
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Joint ache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Feb 2021 23:28:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Feb 2021 23:28:41
Data point term sent to Coder	System	09 Feb 2021 23:27:55
User entered 'joint aches'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:27:54

FDA-CBER-2022-1614-0510108

US3112192
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 15:08:42
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:04
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered 'No (N)'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:27:54

US3112192
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 15:08:42
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:04
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:27:54

US3112192
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 15:08:42
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:04
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered 'No (N)'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:27:54

US3112192
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 15:08:42
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:04
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered '11 Sep 2020'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:27:54

US3112192
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 15:08:42
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:04
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	23 Feb 2021 00:06:54
Query 'Data is required. Please provide.' answered with 'time is unknown ' (Site from System).	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:28:00
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Feb 2021 23:27:54
User entered empty.	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:27:54

US3112192
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 15:08:42
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:04
User entered empty.	System	09 Feb 2021 23:27:54

US3112192
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 15:08:42
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:04
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered 'No (N)'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:27:54

US3112192
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 15:08:42
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:04
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered '01 Oct 2020'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:27:54

US3112192
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 15:08:42
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:04
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	23 Feb 2021 00:06:58
Query 'Data is required. Please provide.' answered with 'time is unknown ' (Site from System).	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:28:04
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Feb 2021 23:27:54
User entered empty.	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:27:54

US3112192
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 15:08:42
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:04
User entered empty.	System	09 Feb 2021 23:27:54

US3112192
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 15:08:42
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:04
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered 'Grade 1/Mild (Grade 1/Mild)'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:27:54

US3112192
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 15:08:42
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:04
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered 'No (N)'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:27:54

US3112192
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 15:08:42
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:04
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered '0'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:27:54

US3112192
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 15:08:42
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:04
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered '0'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:27:54

US3112192
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 15:08:42
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:04
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered '0'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:27:54

US3112192
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 15:08:42
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:04
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered empty.	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:27:54

US3112192
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 15:08:42
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:04
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered empty.	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:27:54

US3112192
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 15:08:42
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:04
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered empty.	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:27:54

US3112192
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 15:08:42
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:04
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered empty.	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:27:54

US3112192
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 15:08:42
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:04
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered '0'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:27:54

US3112192
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 15:08:42
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:04
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered '0'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:27:54

US3112192
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 15:08:42
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:04
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered '0'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:27:54

US3112192
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 15:08:42
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:04
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered 'Related (RELATED)'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:27:54

US3112192
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 15:08:42
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:04
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered 'Not Related (NOT RELATED)'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:27:54

US3112192
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 15:08:42
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:04
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered 'None (NONE)'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:27:54

US3112192
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 15:08:42
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:04
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered '1'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:27:54

US3112192
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 15:08:42
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:04
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered '0'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:27:54

US3112192
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 15:08:42
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:04
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered '0'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:27:54

US3112192
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 15:08:42
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:04
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:27:54

US3112192
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 15:08:42
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:04
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered empty.	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:27:54

US3112192
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 15:08:42
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:04
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered empty.	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:27:54

US3112192
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 15:08:42
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:04
User entered '0'	System	09 Feb 2021 23:27:54

US3112192
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 15:08:42
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:04
User entered '0'	System	09 Feb 2021 23:27:54

US3112192
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 09 Jun 2021 15:08:42
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:04

US3112192
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 15:08:42
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:19

FDA-CBER-2022-1614-0510143

US3112192
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 15:08:42
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:19
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Feb 2021 23:29:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Feb 2021 23:29:43
Data point term sent to Coder	System	09 Feb 2021 23:28:56
User entered 'fatigue'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:28:54

US3112192
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 15:08:42
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:19
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered 'No (N)'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:28:54

US3112192
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 15:08:42
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:19
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:28:54

US3112192
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 15:08:42
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:19
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered 'No (N)'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:28:54

US3112192
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 15:08:42
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:19
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered '11 Sep 2020'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:28:54

US3112192
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 15:08:42
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:19
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	23 Feb 2021 00:07:11
Query 'Data is required. Please provide.' answered with 'time is unknown ' (Site from System).	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:29:01
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Feb 2021 23:28:54
User entered empty.	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:28:54

US3112192
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 15:08:42
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:19
User entered empty.	System	09 Feb 2021 23:28:54

US3112192
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 15:08:42
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:19
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered 'No (N)'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:28:54

US3112192
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 15:08:42
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:19
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered '29 Sep 2020'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:28:54

US3112192
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 15:08:42
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:19
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	23 Feb 2021 00:07:13
Query 'Data is required. Please provide.' answered with 'time is unknown ' (Site from System).	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:29:09
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Feb 2021 23:28:54
User entered empty.	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:28:54

US3112192
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 15:08:42
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:19
User entered empty.	System	09 Feb 2021 23:28:54

US3112192
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 15:08:42
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:19
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:28:54

US3112192
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 15:08:42
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:19
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered 'No (N)'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:28:54

US3112192
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 15:08:42
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:19
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered '0'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:28:54

US3112192
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 15:08:42
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:19
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered '0'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:28:54

US3112192
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 15:08:42
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:19
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered '0'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:28:54

US3112192
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 15:08:42
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:19
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered empty.	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:28:54

US3112192
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 15:08:42
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:19
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered empty.	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:28:54

US3112192
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 15:08:42
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:19
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered empty.	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:28:54

US3112192
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 15:08:42
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:19
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered empty.	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:28:54

US3112192
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 15:08:42
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:19
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered '0'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:28:54

US3112192
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 15:08:42
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:19
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered '0'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:28:54

US3112192
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 15:08:42
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:19
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered '0'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:28:54

US3112192
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 15:08:42
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:19
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered 'Related (RELATED)'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:28:54

US3112192
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 15:08:42
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:19
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered 'Not Related (NOT RELATED)'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:28:54

FDA-CBER-2022-1614-0510168

US3112192
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 15:08:42
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:19
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered 'None (NONE)'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:28:54

US3112192
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 15:08:42
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:19
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered '1'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:28:54

US3112192
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 15:08:42
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:19
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered '0'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:28:54

US3112192
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 15:08:42
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:19
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered '0'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:28:54

US3112192
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 15:08:42
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:19
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:28:54

US3112192
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 15:08:42
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:19
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered empty.	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:28:54

US3112192
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 15:08:42
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:19
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered empty.	Brenda Grande (b) (4) (b) (4)	09 Feb 2021 23:28:54

US3112192
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 15:08:42
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:19
User entered '0'	System	09 Feb 2021 23:28:54

US3112192
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 15:08:42
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:19
User entered '0'	System	09 Feb 2021 23:28:54

US3112192
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 09 Jun 2021 15:08:42
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:19

FDA-CBER-2022-1614-0510178

US3112192
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:08:42
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:22

FDA-CBER-2022-1614-0510179

US3112192
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:08:42
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:22
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation aggravated - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Mar 2021 04:03:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Mar 2021 04:03:50
Data point term sent to Coder	System	10 Mar 2021 22:08:43
User entered 'worsening symptoms of atrial fibrillation'	Brenda Grande (b) (4) (b) (4)	10 Mar 2021 22:08:08

US3112192
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:08:42
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:22
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered 'Yes (Y)'	Brenda Grande (b) (4) (b) (4)	10 Mar 2021 22:08:08

US3112192
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:08:42
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:22
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered 'No (N)'	Brenda Grande (b) (4) (b) (4)	10 Mar 2021 22:08:08

US3112192
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:08:42
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:22
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered 'No (N)'	Brenda Grande (b) (4) (b) (4)	10 Mar 2021 22:08:08

US3112192
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:08:42
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:22
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	10 Mar 2021 22:09:18
User entered '30 Dec 2020' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	10 Mar 2021 22:09:18
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	10 Mar 2021 22:08:08
User entered '30 Dec 2021'	Brenda Grande (b) (4) (b) (4)	10 Mar 2021 22:08:08

US3112192
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:08:42
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:22
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered empty.	Brenda Grande (b) (4) (b) (4)	10 Mar 2021 22:08:08

US3112192
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:08:42
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:22
User entered empty.	System	10 Mar 2021 22:08:08

US3112192
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:08:42
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:22
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered 'No (N)'	Brenda Grande (b) (4) (b) (4)	10 Mar 2021 22:08:08

US3112192
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:08:42
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:22
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User closed query 'End date is prior to Start date. Please correct.' (Site from System).	System	10 Mar 2021 22:09:18
User opened query 'End date is prior to Start date. Please correct.' (Site from System).	System	10 Mar 2021 22:08:08
User entered '23 Feb 2021'	Brenda Grande (b) (4) (b) (4)	10 Mar 2021 22:08:08

US3112192
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:08:42
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:22
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered empty.	Brenda Grande (b) (4) (b) (4)	10 Mar 2021 22:08:08

US3112192
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:08:42
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:22
User entered empty.	System	10 Mar 2021 22:08:08

US3112192
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:08:42
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:22
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered 'Grade 3/Severe (Grade 3/Severe)'	Brenda Grande (b) (4) (b) (4)	10 Mar 2021 22:08:08

US3112192
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:08:42
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:22
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered 'No (N)'	Brenda Grande (b) (4) (b) (4)	10 Mar 2021 22:08:08

US3112192
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:08:42
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:22
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered '0'	Brenda Grande (b) (4) (b) (4)	10 Mar 2021 22:08:08

US3112192
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:08:42
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:22
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered '0'	Brenda Grande (b) (4) (b) (4)	10 Mar 2021 22:08:08

US3112192
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:08:42
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:22
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered '0'	Brenda Grande (b) (4) (b) (4)	10 Mar 2021 22:08:08

US3112192
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:08:42
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:22
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered empty.	Brenda Grande (b) (4) (b) (4)	10 Mar 2021 22:08:08

US3112192
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:08:42
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:22
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered empty.	Brenda Grande (b) (4) (b) (4)	10 Mar 2021 22:08:08

US3112192
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:08:42
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:22
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered empty.	Brenda Grande (b) (4) (b) (4)	10 Mar 2021 22:08:08

US3112192
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:08:42
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:22
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered empty.	Brenda Grande (b) (4) (b) (4)	10 Mar 2021 22:08:08

US3112192
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:08:42
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:22
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered '0'	Brenda Grande (b) (4) (b) (4)	10 Mar 2021 22:08:08

US3112192
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:08:42
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:22
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered '0'	Brenda Grande (b) (4) (b) (4)	10 Mar 2021 22:08:08

US3112192
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:08:42
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:22
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered '0'	Brenda Grande (b) (4) (b) (4)	10 Mar 2021 22:08:08

US3112192
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:08:42
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:22
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered 'Not Related (NOT RELATED)'	Brenda Grande (b) (4) (b) (4)	10 Mar 2021 22:08:08

US3112192
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:08:42
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:22
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered 'Not Related (NOT RELATED)'	Brenda Grande (b) (4) (b) (4)	10 Mar 2021 22:08:08

US3112192
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:08:42
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:22
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered 'None (NONE)'	Brenda Grande (b) (4) (b) (4)	10 Mar 2021 22:08:08

US3112192
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:08:42
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:22
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered '0'	Brenda Grande (b) (4) (b) (4)	10 Mar 2021 22:08:08

US3112192
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:08:42
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:22
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered '0'	Brenda Grande (b) (4) (b) (4)	10 Mar 2021 22:08:08

US3112192
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:08:42
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:22
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered '1'	Brenda Grande (b) (4) (b) (4)	10 Mar 2021 22:08:08

US3112192
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:08:42
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:22
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Brenda Grande (b) (4) (b) (4)	10 Mar 2021 22:08:08

US3112192
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:08:42
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:22
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered empty.	Brenda Grande (b) (4) (b) (4)	10 Mar 2021 22:08:08

US3112192
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:08:42
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:22
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	19 Mar 2021 20:24:11
User entered empty.	Brenda Grande (b) (4) (b) (4)	10 Mar 2021 22:08:08

US3112192
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:08:42
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:22
User entered '0'	System	10 Mar 2021 22:08:08

US3112192
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:08:42
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:22
User entered '1'	System	10 Mar 2021 22:08:08

US3112192
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 09 Jun 2021 15:08:42
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:58:22

FDA-CBER-2022-1614-0510214

US3112192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:08:42

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:44:57
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User closed query 'Per CDM: Per the subject's response Diary Dose 1, 11Aug20, medication was taken to treat pain or fever. Please update the CM page accordingly.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 02:14:55
Query 'Per CDM: Per the subject's response Diary Dose 1, 11Aug20, medication was taken to treat pain or fever. Please update the CM page accordingly.' answered with 'norco for ae updated' (Site from DM).	Natalie Moy (b) (4) (b) (4)	13 Oct 2020 17:01:26
User opened query 'Per CDM: Per the subject's response Diary Dose 1, 11Aug20, medication was taken to treat pain or fever. Please update the CM page accordingly.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 19:32:14
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	12 Aug 2020 00:07:15

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:08:42
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:44:33
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 19:59:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 19:59:59
Data point term sent to Coder	System	25 Sep 2020 19:58:45
Coding entries removed.	Karen Mylerberg (b) (4) (b) (4)	25 Sep 2020 19:58:22
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 00:09:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 00:09:19
Data point term sent to Coder	System	12 Aug 2020 00:08:22
User entered 'Eliquis'	Matthew Musikanth (b) (4)	12 Aug 2020 00:08:06

FDA-CBER-2022-1614-0510216

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:08:42
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:44:38
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 22:27:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 22:27:37
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Aug 2020 22:27:37
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 00:08:06
User entered empty.	Matthew Musikanth (b) (4)	12 Aug 2020 00:08:06

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:08:42
Indication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:44:38
User closed query 'Per CDM: Thank you for your response. Please ensure the MH eCRF is updated accordingly.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 15:41:36
Query 'Per CDM: Thank you for your response. Please ensure the MH eCRF is updated accordingly.' answered with 'med hx updated' (Site from DM).	Karen Mylerberg (b) (4) (b) (4)	30 Sep 2020 18:04:03
User opened query 'Per CDM: Thank you for your response. Please ensure the MH eCRF is updated accordingly.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 19:29:07
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 19:29:07
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' answered with 'updated' (Site from DM).	Karen Mylerberg (b) (4) (b) (4)	25 Sep 2020 19:58:28
User entered 'Atrial fibrillation' reason for change: Data Entry Error	Karen Mylerberg (b) (4) (b) (4)	25 Sep 2020 19:58:22
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 05:23:20
User closed query 'Per DM CLR: Please review Indication and please note that there is no corresponding MH record that match this indication. Please update to record the corresponding condition as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 03:46:53

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:08:42
Indication

Audit	User	Time (GMT)
Query 'Per DM CLR: Please review Indication and please note that there is no corresponding MH record that match this indication. Please update to record the corresponding condition as appropriate. Otherwise, clarify.' answered with 'Updated.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 22:39:29
User opened query 'Per DM CLR: Please review Indication and please note that there is no corresponding MH record that match this indication. Please update to record the corresponding condition as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 01:30:07
User entered 'Bowel Blockage'	Matthew Musikanth (b) (4)	12 Aug 2020 00:08:06

FDA-CBER-2022-1614-0510219

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:08:42
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:44:38
User entered '5'	Matthew Musikanth (b) (4)	12 Aug 2020 00:08:06

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:08:42
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:44:38
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	12 Aug 2020 00:08:06

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:08:42
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:44:38
User entered empty.	Matthew Musikanth (b) (4)	12 Aug 2020 00:08:06

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:08:42
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:44:38
User entered 'twice daily (BID)'	Matthew Musikanth (b) (4)	12 Aug 2020 00:08:06

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:08:42
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:44:38
User entered empty.	Matthew Musikanth (b) (4)	12 Aug 2020 00:08:06

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:08:42
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:44:38
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	12 Aug 2020 00:08:06

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:08:42
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:44:38
User entered empty.	Matthew Musikanth (b) (4)	12 Aug 2020 00:08:06

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:08:42
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:44:38
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	13 Aug 2020 10:36:45
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 00:08:06
User entered '12 Apr 2020'	Matthew Musikanth (b) (4)	12 Aug 2020 00:08:06

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:08:42
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:44:38
User entered '0'	Matthew Musikanth (b) (4)	12 Aug 2020 00:08:06

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:08:42
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:44:38
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	12 Aug 2020 00:08:06

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:08:42
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:44:38
User entered empty.	Matthew Musikanth (b) (4)	12 Aug 2020 00:08:06

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:08:42
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:44:38
User entered 'No (N)'	Matthew Musikanth (b) (4)	12 Aug 2020 00:08:06

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:08:42
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	12 Aug 2020 00:08:06

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:08:42
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 00:08:06

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 15:08:42
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 00:08:06

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:08:42
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 00:10:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 00:10:19
Data point term sent to Coder	System	12 Aug 2020 00:09:23
User entered 'Losartan'	Matthew Musikanth (b) (4)	12 Aug 2020 00:09:01

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:08:42
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'No (N)'	Matthew Musikanth (b) (4)	12 Aug 2020 00:09:01

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:08:42
Indication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User closed query 'Per DM CLR: Please review Indication and please note that there is no corresponding MH record that match this indication. Please update to record the corresponding condition as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 03:47:04
Query 'Per DM CLR: Please review Indication and please note that there is no corresponding MH record that match this indication. Please update to record the corresponding condition as appropriate. Otherwise, clarify.' answered with 'Updated.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 22:39:35
User opened query 'Per DM CLR: Please review Indication and please note that there is no corresponding MH record that match this indication. Please update to record the corresponding condition as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 01:30:41
User entered 'Hypertension'	Matthew Musikanth (b) (4)	12 Aug 2020 00:09:01

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:08:42
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered '100'	Matthew Musikanth (b) (4)	12 Aug 2020 00:09:01

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:08:42
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	12 Aug 2020 00:09:01

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:08:42
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Matthew Musikanth (b) (4)	12 Aug 2020 00:09:01

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:08:42
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'once daily (QD)'	Matthew Musikanth (b) (4)	12 Aug 2020 00:09:01

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:08:42
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Matthew Musikanth (b) (4)	12 Aug 2020 00:09:01

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:08:42
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	12 Aug 2020 00:09:01

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:08:42
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Matthew Musikanth (b) (4)	12 Aug 2020 00:09:01

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:08:42
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	13 Aug 2020 10:37:09
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 00:09:01
User entered '12 Apr 2020'	Matthew Musikanth (b) (4)	12 Aug 2020 00:09:01

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:08:42
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered '0'	Matthew Musikanth (b) (4)	12 Aug 2020 00:09:01

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:08:42
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	12 Aug 2020 00:09:01

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:08:42
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Matthew Musikanth (b) (4)	12 Aug 2020 00:09:01

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:08:42
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'No (N)'	Matthew Musikanth (b) (4)	12 Aug 2020 00:09:01

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:08:42
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 00:09:01

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:08:42
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 00:09:01

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 15:08:42
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 00:09:01

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 15:08:42
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 00:11:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 00:11:19
Data point term sent to Coder	System	12 Aug 2020 00:10:24
User entered 'Vitamin C'	Matthew Musikanth (b) (4)	12 Aug 2020 00:09:39

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 15:08:42
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'No (N)'	Matthew Musikanth (b) (4)	12 Aug 2020 00:09:39

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 15:08:42
Indication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'Supplement'	Matthew Musikanth (b) (4)	12 Aug 2020 00:09:39

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 15:08:42
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered '1000'	Matthew Musikanth (b) (4)	12 Aug 2020 00:09:39

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 15:08:42
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	12 Aug 2020 00:09:39

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 15:08:42
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Matthew Musikanth (b) (4)	12 Aug 2020 00:09:39

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 15:08:42
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'once daily (QD)'	Matthew Musikanth (b) (4)	12 Aug 2020 00:09:39

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 15:08:42
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Matthew Musikanth (b) (4)	12 Aug 2020 00:09:39

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 15:08:42
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	12 Aug 2020 00:09:39

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 15:08:42
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Matthew Musikanth (b) (4)	12 Aug 2020 00:09:39

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 15:08:42
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	13 Aug 2020 10:37:28
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 00:09:39
User entered 'un UNK 2005'	Matthew Musikanth (b) (4)	12 Aug 2020 00:09:39

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 15:08:42
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered '0'	Matthew Musikanth (b) (4)	12 Aug 2020 00:09:39

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 15:08:42
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	12 Aug 2020 00:09:39

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 15:08:42
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Matthew Musikanth (b) (4)	12 Aug 2020 00:09:39

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 15:08:42
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'No (N)'	Matthew Musikanth (b) (4)	12 Aug 2020 00:09:39

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 15:08:42
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 00:09:39

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 15:08:42
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 00:09:39

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 15:08:42
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 00:09:39

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 15:08:42
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 06:52:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 06:52:10
Data point term sent to Coder	System	12 Aug 2020 00:10:24
User entered 'Multi Vitamin'	Matthew Musikanth (b) (4)	12 Aug 2020 00:10:15

FDA-CBER-2022-1614-0510271

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 15:08:42
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'No (N)'	Matthew Musikanth (b) (4)	12 Aug 2020 00:10:15

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 15:08:42
Indication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'Supplement'	Matthew Musikanth (b) (4)	12 Aug 2020 00:10:15

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 15:08:42
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered '1'	Matthew Musikanth (b) (4)	12 Aug 2020 00:10:15

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 15:08:42
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'tablet (TABLET)'	Matthew Musikanth (b) (4)	12 Aug 2020 00:10:15

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 15:08:42
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Matthew Musikanth (b) (4)	12 Aug 2020 00:10:15

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 15:08:42
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'once daily (QD)'	Matthew Musikanth (b) (4)	12 Aug 2020 00:10:15

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 15:08:42
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Matthew Musikanth (b) (4)	12 Aug 2020 00:10:15

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 15:08:42
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	12 Aug 2020 00:10:15

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 15:08:42
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Matthew Musikanth (b) (4)	12 Aug 2020 00:10:15

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 15:08:42
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	13 Aug 2020 10:38:10
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	12 Aug 2020 00:10:15
User entered 'un UNK 2000'	Matthew Musikanth (b) (4)	12 Aug 2020 00:10:15

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 15:08:42
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered '0'	Matthew Musikanth (b) (4)	12 Aug 2020 00:10:15

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 15:08:42
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	12 Aug 2020 00:10:15

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 15:08:42
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Matthew Musikanth (b) (4)	12 Aug 2020 00:10:15

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 15:08:42
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'No (N)'	Matthew Musikanth (b) (4)	12 Aug 2020 00:10:15

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 15:08:42
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 00:10:15

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 15:08:42
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 00:10:15

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 15:08:42
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 00:10:15

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 15:08:42
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: NORCO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 19:05:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 19:05:38
Data point term sent to Coder	System	18 Sep 2020 19:04:42
User entered 'Norco'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:04:17

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 15:08:42
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'No (N)'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:04:17

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 15:08:42
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'Left knee contusion secondary to mechanical fall'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:04:17

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 15:08:42
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered '10/325'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:04:17

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 15:08:42
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'mg (mg)'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:04:17

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 15:08:42
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:04:17

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 15:08:42
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'as needed (PRN)'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:04:17

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 15:08:42
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:04:17

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 15:08:42
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'Oral (ORAL)'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:04:17

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 15:08:42
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:04:17

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 15:08:42
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered '2 Sep 2020'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:04:17

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 15:08:42
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered '0'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:04:17

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 15:08:42
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 18:43:03
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'has been updated ' (Site from DM).	Brenda Grande (b) (4) (b) (4)	14 Jan 2021 23:46:46
User entered 'No (N)' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	14 Jan 2021 23:46:12
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 23:43:09
User entered 'Yes (Y)'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:04:17

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 15:08:42
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered '16 Sep 2020' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	14 Jan 2021 23:46:12
User entered empty.	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:04:17

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 15:08:42
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:44
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'No (N)'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:04:17

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 15:08:42
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:44
User entered empty.	System	18 Sep 2020 19:04:17

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 15:08:42
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:44
User entered empty.	System	18 Sep 2020 19:04:17

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 15:08:42
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:44
User entered empty.	System	18 Sep 2020 19:04:17

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 15:08:42
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:48
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 23:17:37
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 Sep 2020 23:17:37
Data point term sent to Coder	System	18 Sep 2020 19:05:46
User entered 'Morphine'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:05:16

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 15:08:42
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:48
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'No (N)'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:05:16

FDA-CBER-2022-1614-0510308

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 15:08:42
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:48
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'Left knee contusion secondary to mechanical fall'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:05:16

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 15:08:42
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:48
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered '10'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:05:16

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 15:08:42
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:48
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'mg (mg)'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:05:16

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 15:08:42
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:48
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:05:16

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 15:08:42
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:48
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'as needed (PRN)'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:05:16

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 15:08:42
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:48
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:05:16

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 15:08:42
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:48
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'Oral (ORAL)'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:05:16

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 15:08:42
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:48
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:05:16

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 15:08:42
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:48
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered '2 Sep 2020'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:05:16

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 15:08:42
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:48
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered '0'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:05:16

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 15:08:42
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:48
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 18:43:14
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'has been updated ' (Site from DM).	Brenda Grande (b) (4) (b) (4)	14 Jan 2021 23:50:13
User entered 'No (N)' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	14 Jan 2021 23:49:58
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 23:43:30
User entered 'Yes (Y)'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:05:16

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 15:08:42
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:48
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered '16 Sep 2020' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	14 Jan 2021 23:49:58
User entered empty.	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:05:16

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 15:08:42
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:48
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'No (N)'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:05:16

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 15:08:42
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:48
User entered empty.	System	18 Sep 2020 19:05:16

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 15:08:42
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:48
User entered empty.	System	18 Sep 2020 19:05:16

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 15:08:42
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:48
User entered empty.	System	18 Sep 2020 19:05:16

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 15:08:42
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:33
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: NORCO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 19:07:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 19:07:42
Data point term sent to Coder	System	18 Sep 2020 19:06:48
User entered 'norco'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:06:25

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 15:08:42
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:33
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'No (N)'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:06:25

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 15:08:42
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:33
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'left shoulder contusion secondary to mechanical fall'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:06:25

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 15:08:42
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:33
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered '10/325'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:06:25

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 15:08:42
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:33
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'mg (mg)'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:06:25

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 15:08:42
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:33
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:06:25

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 15:08:42
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:33
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'as needed (PRN)'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:06:25

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 15:08:42
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:33
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:06:25

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 15:08:42
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:33
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'Oral (ORAL)'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:06:25

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 15:08:42
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:33
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:06:25

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 15:08:42
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:33
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered '02 Sep 2020'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:06:25

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 15:08:42
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:33
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered '0'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:06:25

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 15:08:42
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:33
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 18:43:26
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'has been updated ' (Site from DM).	Brenda Grande (b) (4) (b) (4)	14 Jan 2021 23:52:28
User entered 'No (N)' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	14 Jan 2021 23:51:44
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 23:45:34
User entered 'Yes (Y)'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:06:25

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 15:08:42
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:33
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered '16 Sep 2020' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	14 Jan 2021 23:51:44
User entered empty.	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:06:25

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 15:08:42
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:33
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'No (N)'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:06:25

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 15:08:42
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:33
User entered empty.	System	18 Sep 2020 19:06:25

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 15:08:42
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:33
User entered empty.	System	18 Sep 2020 19:06:25

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 15:08:42
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:33
User entered empty.	System	18 Sep 2020 19:06:25

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 15:08:42
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:38
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 23:17:37
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 Sep 2020 23:17:37
Data point term sent to Coder	System	18 Sep 2020 19:07:50
User entered 'morphine'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:07:20

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 15:08:42
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:38
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'No (N)'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:07:20

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 15:08:42
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:38
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'left shoulder contusion secondary to mechanical fall'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:07:20

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 15:08:42
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:38
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered '10'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:07:20

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 15:08:42
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:38
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'mg (mg)'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:07:20

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 15:08:42
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:38
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:07:20

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 15:08:42
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:38
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'as needed (PRN)'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:07:20

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 15:08:42
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:38
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:07:20

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 15:08:42
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:38
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'Oral (ORAL)'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:07:20

FDA-CBER-2022-1614-0510351

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 15:08:42
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:38
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:07:20

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 15:08:42
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:38
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered '02 Sep 2020'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:07:20

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 15:08:42
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:38
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered '0'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:07:20

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 15:08:42
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:38
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 18:43:40
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'has been updated ' (Site from DM).	Brenda Grande (b) (4) (b) (4)	14 Jan 2021 23:54:05
User entered 'No (N)' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	14 Jan 2021 23:53:43
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 23:45:43
User entered 'Yes (Y)'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:07:20

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 15:08:42
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:38
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered '16 Sep 2020' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	14 Jan 2021 23:53:43
User entered empty.	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:07:20

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 15:08:42
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:38
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'No (N)'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:07:20

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 15:08:42
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:38
User entered empty.	System	18 Sep 2020 19:07:20

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 15:08:42
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:38
User entered empty.	System	18 Sep 2020 19:07:20

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 15:08:42
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:38
User entered empty.	System	18 Sep 2020 19:07:20

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 15:08:42
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:14:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 18:06:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 18:06:49
Data point term sent to Coder	System	30 Sep 2020 18:06:28
User entered 'amlodipine'	Karen Mylerberg (b) (4) (b) (4)	30 Sep 2020 18:06:05

FDA-CBER-2022-1614-0510361

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 15:08:42
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:14:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	30 Sep 2020 18:06:05

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 15:08:42
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:14:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'hypertension'	Karen Mylerberg (b) (4) (b) (4)	30 Sep 2020 18:06:05

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 15:08:42
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:14:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered '54'	Karen Mylerberg (b) (4) (b) (4)	30 Sep 2020 18:06:05

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 15:08:42
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:14:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'mg (mg)'	Karen Mylerberg (b) (4) (b) (4)	30 Sep 2020 18:06:05

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 15:08:42
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:14:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	30 Sep 2020 18:06:05

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 15:08:42
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:14:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'once daily (QD)'	Karen Mylerberg (b) (4) (b) (4)	30 Sep 2020 18:06:05

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 15:08:42
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:14:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	30 Sep 2020 18:06:05

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 15:08:42
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:14:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'Oral (ORAL)'	Karen Mylerberg (b) (4) (b) (4)	30 Sep 2020 18:06:05

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 15:08:42
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:14:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	30 Sep 2020 18:06:05

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 15:08:42
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:14:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered '12 Apr 2020'	Karen Mylerberg (b) (4) (b) (4)	30 Sep 2020 18:06:05

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 15:08:42
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:14:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered '0'	Karen Mylerberg (b) (4) (b) (4)	30 Sep 2020 18:06:05

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 15:08:42
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:14:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	30 Sep 2020 18:06:05

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 15:08:42
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:14:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered '23 Sep 2020'	Karen Mylerberg (b) (4) (b) (4)	30 Sep 2020 18:06:05

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 15:08:42
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:14:02
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	30 Sep 2020 18:06:05

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 15:08:42
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:14:02
User entered '1'	System	30 Sep 2020 18:06:05

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 15:08:42
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:14:02
User entered '1'	System	30 Sep 2020 18:06:05

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 15:08:42
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:14:02
User entered '804 (804)'	System	30 Sep 2020 18:06:05

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 15:08:42
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 18:08:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 18:08:52
Data point term sent to Coder	System	30 Sep 2020 18:07:34
User entered 'atorvastatin'	Karen Mylerberg (b) (4) (b) (4)	30 Sep 2020 18:06:44

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 15:08:42
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'No (N)'	Karen Mylerberg (b) (4) (b) (4)	30 Sep 2020 18:06:44

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 15:08:42
Indication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'hypercholesterolemia'	Karen Mylerberg (b) (4) (b) (4)	30 Sep 2020 18:06:44

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 15:08:42
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered '10'	Karen Mylerberg (b) (4) (b) (4)	30 Sep 2020 18:06:44

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 15:08:42
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'mg (mg)'	Karen Mylerberg (b) (4) (b) (4)	30 Sep 2020 18:06:44

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 15:08:42
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	30 Sep 2020 18:06:44

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 15:08:42
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'once daily (QD)'	Karen Mylerberg (b) (4) (b) (4)	30 Sep 2020 18:06:44

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 15:08:42
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	30 Sep 2020 18:06:44

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 15:08:42
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'Oral (ORAL)'	Karen Mylerberg (b) (4) (b) (4)	30 Sep 2020 18:06:44

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 15:08:42
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	30 Sep 2020 18:06:44

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 15:08:42
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered '25 Sep 2020'	Karen Mylerberg (b) (4) (b) (4)	30 Sep 2020 18:06:44

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 15:08:42
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered '0'	Karen Mylerberg (b) (4) (b) (4)	30 Sep 2020 18:06:44

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 15:08:42
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	30 Sep 2020 18:06:44

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 15:08:42
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	30 Sep 2020 18:06:44

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 15:08:42
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 18:07:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Sep 2020 18:07:18
User entered 'No (N)' reason for change: Data Entry Error	Karen Mylerberg (b) (4) (b) (4)	30 Sep 2020 18:07:18
User opened query 'Data is required. Please complete.' (Site from System).	System	30 Sep 2020 18:06:44
User entered empty.	Karen Mylerberg (b) (4) (b) (4)	30 Sep 2020 18:06:44

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 15:08:42
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 18:06:44

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 15:08:42
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 18:06:44

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 15:08:42
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Sep 2020 18:06:44

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 15:08:42
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:14:07
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 23:21:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 23:21:43
Data point term sent to Coder	System	08 Oct 2020 16:13:46
User entered 'tylenol'	Natalie Moy (b) (4) (b) (4)	08 Oct 2020 16:13:39

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 15:08:42
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:14:07
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'No (N)'	Natalie Moy (b) (4) (b) (4)	08 Oct 2020 16:13:39

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 15:08:42
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:14:07
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'body aches prior to injection'	Natalie Moy (b) (4) (b) (4)	08 Oct 2020 16:13:39

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 15:08:42
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:14:07
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered '500'	Natalie Moy (b) (4) (b) (4)	08 Oct 2020 16:13:39

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 15:08:42
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:14:07
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'mg (mg)'	Natalie Moy (b) (4) (b) (4)	08 Oct 2020 16:13:39

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 15:08:42
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:14:07
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Natalie Moy (b) (4) (b) (4)	08 Oct 2020 16:13:39

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 15:08:42
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:14:07
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'as needed (PRN)'	Natalie Moy (b) (4) (b) (4)	08 Oct 2020 16:13:39

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 15:08:42
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:14:07
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Natalie Moy (b) (4) (b) (4)	08 Oct 2020 16:13:39

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 15:08:42
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:14:07
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'Oral (ORAL)'	Natalie Moy (b) (4) (b) (4)	08 Oct 2020 16:13:39

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 15:08:42
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:14:07
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Natalie Moy (b) (4) (b) (4)	08 Oct 2020 16:13:39

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 15:08:42
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:14:07
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered '11 Aug 2020'	Natalie Moy (b) (4) (b) (4)	08 Oct 2020 16:13:39

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 15:08:42
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:14:07
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered '0'	Natalie Moy (b) (4) (b) (4)	08 Oct 2020 16:13:39

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 15:08:42
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:14:07
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'No (N)'	Natalie Moy (b) (4) (b) (4)	08 Oct 2020 16:13:39

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 15:08:42
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:14:07
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered '13 Aug 2020'	Natalie Moy (b) (4) (b) (4)	08 Oct 2020 16:13:39

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 15:08:42
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:14:07
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	08 Oct 2020 16:13:39

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 15:08:42
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:14:07
User entered empty.	System	08 Oct 2020 16:13:39

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 15:08:42
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:14:07
User entered empty.	System	08 Oct 2020 16:13:39

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 15:08:42
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:14:07
User entered empty.	System	08 Oct 2020 16:13:39

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 15:08:42
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
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 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 21:33:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 21:33:40
Data point term sent to Coder	System	10 Nov 2020 21:33:06
Coding entries removed.	Natalie Moy (b) (4) (b) (4)	10 Nov 2020 21:32:52
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 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 19:09:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 19:09:21
Data point term sent to Coder	System	05 Nov 2020 19:08:04
User entered 'montelukast'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:07:32

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 15:08:42
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'No (N)'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:07:32

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 15:08:42
Indication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'Asthma' reason for change: Data Entry Error	Natalie Moy (b) (4) (b) (4)	10 Nov 2020 21:32:52
User entered 'allergies'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:07:32

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 15:08:42
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered '10'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:07:32

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 15:08:42
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'mg (mg)'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:07:32

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 15:08:42
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:07:32

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 15:08:42
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'as needed (PRN)' reason for change: Data Entry Error	Natalie Moy (b) (4) (b) (4)	10 Nov 2020 21:33:39
User entered 'once daily (QD)'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:07:32

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 15:08:42
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:07:32

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 15:08:42
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'Oral (ORAL)'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:07:32

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 15:08:42
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:07:32

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 15:08:42
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:07:32

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 15:08:42
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered '1'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:07:32

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 15:08:42
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:07:32

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 15:08:42
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:07:32

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 15:08:42
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'No (N)'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:07:32

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 15:08:42
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 21:33:39
User entered '1'	System	05 Nov 2020 19:07:32

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 15:08:42
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 21:33:39
User entered '1'	System	05 Nov 2020 19:07:32

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 15:08:42
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 21:33:39
User entered '804 (804)'	System	05 Nov 2020 19:07:32

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 15:08:42
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: DULOXETINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 19:10:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 19:10:22
Data point term sent to Coder	System	05 Nov 2020 19:09:07
User entered 'Duloxetine'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:08:36

FDA-CBER-2022-1614-0510433

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 15:08:42
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'No (N)'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:08:36

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 15:08:42
Indication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'Depression'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:08:36

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 15:08:42
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered '20'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:08:36

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 15:08:42
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'mg (mg)'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:08:36

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 15:08:42
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:08:36

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 15:08:42
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'once daily (QD)'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:08:36

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 15:08:42
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:08:36

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 15:08:42
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'Oral (ORAL)'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:08:36

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 15:08:42
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:08:36

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 15:08:42
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered '20 Oct 2020'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:08:36

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 15:08:42
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered '0'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:08:36

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 15:08:42
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:08:36

FDA-CBER-2022-1614-0510445

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 15:08:42
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:08:36

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 15:08:42
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'No (N)'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:08:36

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 15:08:42
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 19:08:36

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 15:08:42
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 19:08:36

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 15:08:42
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Nov 2020 19:08:36

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 15:08:42
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Dec 2020 22:46:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Dec 2020 22:46:57
Data point term sent to Coder	System	16 Dec 2020 22:46:41
Coding entries removed.	Brenda Grande (b) (4) (b) (4)	16 Dec 2020 22:46:20
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 19:11:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 19:11:22
Data point term sent to Coder	System	05 Nov 2020 19:10:09
User entered 'albuterol'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:09:39

FDA-CBER-2022-1614-0510451

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 15:08:42
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'No (N)'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:09:39

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 15:08:42
Indication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User closed query '"Per DM CLR: Please update the indication to reflect the location/type of ALLERGIES. Please reconcile with the AE and Med History eCRFs as appropriate."' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 13:51:07
Query '"Per DM CLR: Please update the indication to reflect the location/type of ALLERGIES. Please reconcile with the AE and Med History eCRFs as appropriate."' answered with 'has been updated ' (Site from DM).	Brenda Grande (b) (4) (b) (4)	16 Dec 2020 22:46:47
User entered 'seasonal ALLERGIES' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	16 Dec 2020 22:46:20
User opened query '"Per DM CLR: Please update the indication to reflect the location/type of ALLERGIES. Please reconcile with the AE and Med History eCRFs as appropriate."' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 06:57:02
User entered 'allergies'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:09:39

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 15:08:42
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered '1'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:09:39

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 15:08:42
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'puff (PUFF)'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:09:39

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 15:08:42
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:09:39

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 15:08:42
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'as needed (PRN)'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:09:39

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 15:08:42
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:09:39

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 15:08:42
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:09:39

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 15:08:42
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:09:39

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 15:08:42
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered '18 Oct 2020'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:09:39

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 15:08:42
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered '0'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:09:39

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 15:08:42
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:09:39

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 15:08:42
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:09:39

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 15:08:42
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'No (N)'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:09:39

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 15:08:42
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 19:09:39

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 15:08:42
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 19:09:39

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 15:08:42
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 19:09:39

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 15:08:42
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
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: LORATADINE, PRODUCTSYNONYM: CLARITIN [LORATADINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Dec 2020 22:48:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Dec 2020 22:48:10
Data point term sent to Coder	System	16 Dec 2020 22:47:41
Coding entries removed.	Brenda Grande (b) (4) (b) (4)	16 Dec 2020 22:47:09
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: LORATADINE, PRODUCTSYNONYM: CLARITIN [LORATADINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 19:12:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 19:12:21
Data point term sent to Coder	System	05 Nov 2020 19:11:10
User entered 'claritin'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:10:21

FDA-CBER-2022-1614-0510469

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 15:08:42
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'No (N)'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:10:21

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 15:08:42
Indication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User closed query '"Per DM CLR: Please update the indication to reflect the location/type of ALLERGIES. Please reconcile with the AE and Med History eCRFs as appropriate."' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 13:51:23
Query '"Per DM CLR: Please update the indication to reflect the location/type of ALLERGIES. Please reconcile with the AE and Med History eCRFs as appropriate."' answered with 'has been updated ' (Site from DM).	Brenda Grande (b) (4) (b) (4)	16 Dec 2020 22:47:22
User entered 'seasonal ALLERGIES' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	16 Dec 2020 22:47:09
User opened query '"Per DM CLR: Please update the indication to reflect the location/type of ALLERGIES. Please reconcile with the AE and Med History eCRFs as appropriate."' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 06:57:43
User entered 'allergies'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:10:21

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 15:08:42
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered '10'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:10:21

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 15:08:42
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'mg (mg)'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:10:21

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 15:08:42
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:10:21

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 15:08:42
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'as needed (PRN)'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:10:21

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 15:08:42
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:10:21

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 15:08:42
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'Oral (ORAL)'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:10:21

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 15:08:42
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:10:21

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 15:08:42
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:10:21

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 15:08:42
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered '1'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:10:21

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 15:08:42
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:10:21

FDA-CBER-2022-1614-0510481

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 15:08:42
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:10:21

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 15:08:42
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'No (N)'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:10:21

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 15:08:42
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 19:10:21

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 15:08:42
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 19:10:21

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 15:08:42
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 19:10:21

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 15:08:42
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOIDS, PRODUCT: FLUTICASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 19:26:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 19:26:50
Data point term sent to Coder	System	16 Dec 2020 22:48:42
Coding entries removed.	Brenda Grande (b) (4) (b) (4)	16 Dec 2020 22:48:18
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOIDS, PRODUCT: FLUTICASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 03:49:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 03:49:44
Data point term sent to Coder	System	05 Nov 2020 19:11:10
User entered 'Fluticazone Diskus'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:11:09

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 15:08:42
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'No (N)'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:11:09

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 15:08:42
Indication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User closed query '"Per DM CLR: Please update the indication to reflect the location/type of ALLERGIES. Please reconcile with the AE and Med History eCRFs as appropriate."' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 13:51:37
User entered 'SEASONAL allergies' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	16 Dec 2020 22:48:18
Query '"Per DM CLR: Please update the indication to reflect the location/type of ALLERGIES. Please reconcile with the AE and Med History eCRFs as appropriate."' answered with 'seasonal allergies ' (Site from DM).	Brenda Grande (b) (4) (b) (4)	16 Dec 2020 22:47:47
User opened query '"Per DM CLR: Please update the indication to reflect the location/type of ALLERGIES. Please reconcile with the AE and Med History eCRFs as appropriate."' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 06:58:34
User entered 'allergies'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:11:09

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 15:08:42
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered '250'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:11:09

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 15:08:42
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'ug (ug)'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:11:09

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 15:08:42
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:11:09

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 15:08:42
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'twice daily (BID)'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:11:09

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 15:08:42
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:11:09

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 15:08:42
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:11:09

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 15:08:42
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:11:09

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 15:08:42
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered '21 Oct 2020'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:11:09

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 15:08:42
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered '0'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:11:09

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 15:08:42
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:11:09

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 15:08:42
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:11:09

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 15:08:42
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'No (N)'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:11:09

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 15:08:42
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	05 Nov 2020 19:11:09

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 15:08:42
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 19:11:09

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 15:08:42
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Nov 2020 19:11:09

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 15:08:42
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Jan 2021 01:02:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Jan 2021 01:02:09
Data point term sent to Coder	System	27 Jan 2021 19:14:28
Coding entries removed.	Natalie Moy (b) (4) (b) (4)	27 Jan 2021 19:13:37
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOIDS, PRODUCT: FLUTICASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 19:25:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 19:25:52
Data point term sent to Coder	System	16 Dec 2020 22:49:43
Coding entries removed.	Brenda Grande (b) (4) (b) (4)	16 Dec 2020 22:48:53
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLUTICASONE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 22:36:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 22:36:30
Data point term sent to Coder	System	05 Nov 2020 19:12:12

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 15:08:42
Name of Medication

Audit	User	Time (GMT)
User entered 'Fluticazone'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:11:45

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 15:08:42
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'No (N)'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:11:45

FDA-CBER-2022-1614-0510507

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 15:08:42
Indication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User closed query '"Per DM CLR: Please update the indication to reflect the location/type of ALLERGIES. Please reconcile with the AE and Med History eCRFs as appropriate."' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 13:51:48
Query '"Per DM CLR: Please update the indication to reflect the location/type of ALLERGIES. Please reconcile with the AE and Med History eCRFs as appropriate."' answered with 'has been updated ' (Site from DM).	Brenda Grande (b) (4) (b) (4)	16 Dec 2020 22:49:05
User entered 'SEASONAL ALLERGIES' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	16 Dec 2020 22:48:53
User opened query '"Per DM CLR: Please update the indication to reflect the location/type of ALLERGIES. Please reconcile with the AE and Med History eCRFs as appropriate."' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 06:59:06
User entered 'allergies'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:11:45

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 15:08:42
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered '50'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:11:45

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 15:08:42
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'ug (ug)'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:11:45

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 15:08:42
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:11:45

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 15:08:42
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'twice daily (BID)'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:11:45

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 15:08:42
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:11:45

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 15:08:42
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User closed query 'Per DM CLR: Please review route, as this is not the expected route for this medication. Please verify if Nasal would be more appropriate route for this type of medication. If so, review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 12:29:43
Query 'Per DM CLR: Please review route, as this is not the expected route for this medication. Please verify if Nasal would be more appropriate route for this type of medication. If so, review and update as appropriate.' answered with 'updated thank you ' (Site from DM).	Natalie Moy (b) (4) (b) (4)	27 Jan 2021 19:14:03
User entered 'Nasal (NASAL)' reason for change: Data Entry Error	Natalie Moy (b) (4) (b) (4)	27 Jan 2021 19:13:37
User opened query 'Per DM CLR: Please review route, as this is not the expected route for this medication. Please verify if Nasal would be more appropriate route for this type of medication. If so, review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 03:23:50
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:11:45

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 15:08:42
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:11:45

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 15:08:42
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:11:45

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 15:08:42
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered '1'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:11:45

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 15:08:42
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:11:45

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 15:08:42
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:11:45

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 15:08:42
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'No (N)'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:11:45

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 15:08:42
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	05 Nov 2020 19:11:45

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 15:08:42
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 19:11:45

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 15:08:42
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Nov 2020 19:11:45

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 15:08:42
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history of ATRIAL FIBRILLATION worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 03:12:20
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history of ATRIAL FIBRILLATION worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate.' answered with 'per prog note, pt had an SAE as they took BP at home and was in excess of 195 systolic. went in for atrial fibrillation per SAE' (Site from DM).	Natalie Moy (b) (4) (b) (4)	27 Jan 2021 19:19:26
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history of ATRIAL FIBRILLATION worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 03:25:06
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: ANTIARRHYTHMICS, CLASS I AND III, ATC: ANTIARRHYTHMICS, CLASS III, PRODUCT: AMIODARONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 19:13:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 19:13:47
Data point term sent to Coder	System	17 Dec 2020 19:12:52
Coding entries removed.	Brenda Grande (b) (4) (b) (4)	17 Dec 2020 19:11:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 23:52:35

US3112192

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:08:42

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: ANTIARRHYTHMICS, CLASS I AND III, ATC: ANTIARRHYTHMICS, CLASS III, PRODUCT: AMIODARONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 20:15:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 20:15:25
Data point term sent to Coder	System	05 Nov 2020 19:13:13
User entered 'amiodarone'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:12:27

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 15:08:42
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 23:53:19
User entered 'No (N)'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:12:27

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 15:08:42
Indication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the drug class or action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 13:52:12
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the drug class or action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' answered with 'updated' (Site from DM).	Brenda Grande (b) (4) (b) (4)	17 Dec 2020 19:12:12
DataPoint Un-verified.	Brenda Grande (b) (4) (b) (4)	17 Dec 2020 19:11:53
User entered 'atrial fibrillation' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	17 Dec 2020 19:11:53
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the drug class or action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 06:59:45
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 23:53:19
User entered 'heart rhythm regulator'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:12:27

FDA-CBER-2022-1614-0510527

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 15:08:42
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 23:53:19
User entered '200'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:12:27

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 15:08:42
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 23:53:19
User entered 'mg (mg)'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:12:27

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 15:08:42
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 23:53:19
User entered empty.	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:12:27

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 15:08:42
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 23:53:19
User entered 'once daily (QD)'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:12:27

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 15:08:42
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 23:53:19
User entered empty.	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:12:27

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 15:08:42
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 23:53:19
User entered 'Oral (ORAL)'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:12:27

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 15:08:42
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 23:53:19
User entered empty.	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:12:27

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 15:08:42
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 23:53:19
User entered '18 Oct 2020'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:12:27

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 15:08:42
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 23:53:19
User entered '0'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:12:27

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 15:08:42
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 23:53:19
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:12:27

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 15:08:42
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 23:53:19
User entered empty.	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:12:27

FDA-CBER-2022-1614-0510538

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 15:08:42
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 23:53:19
User entered 'No (N)'	Natalie Moy (b) (4) (b) (4)	05 Nov 2020 19:12:27

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 15:08:42
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 19:12:27

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 15:08:42
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 19:12:27

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 15:08:42
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Nov 2020 19:12:27

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 15:08:42
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:55
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 23:52:56
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 06:25:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 06:25:29
Data point term sent to Coder	System	05 Nov 2020 23:15:16
User entered 'aspirin'	Matthew Musikanth (b) (4)	05 Nov 2020 23:14:28

FDA-CBER-2022-1614-0510543

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 15:08:42
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:55
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 23:53:16
User entered 'No (N)'	Matthew Musikanth (b) (4)	05 Nov 2020 23:14:28

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 15:08:42
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:55
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 23:53:16
User entered 'Paroxysmal Atrial Fibrillation'	Matthew Musikanth (b) (4)	05 Nov 2020 23:14:28

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 15:08:42
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:55
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 23:53:16
User entered '325'	Matthew Musikanth (b) (4)	05 Nov 2020 23:14:28

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 15:08:42
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:55
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 23:53:16
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	05 Nov 2020 23:14:28

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 15:08:42
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:55
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 23:53:16
User entered empty.	Matthew Musikanth (b) (4)	05 Nov 2020 23:14:28

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 15:08:42
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:55
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 23:53:16
User entered 'once (ONCE)'	Matthew Musikanth (b) (4)	05 Nov 2020 23:14:28

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 15:08:42
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:55
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 23:53:16
User entered empty.	Matthew Musikanth (b) (4)	05 Nov 2020 23:14:28

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 15:08:42
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:55
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 23:53:16
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	05 Nov 2020 23:14:28

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 15:08:42
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:55
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 23:53:16
User entered empty.	Matthew Musikanth (b) (4)	05 Nov 2020 23:14:28

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 15:08:42
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:55
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 23:53:16
User entered '18 Oct 2020'	Matthew Musikanth (b) (4)	05 Nov 2020 23:14:28

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 15:08:42
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:55
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 23:53:16
User entered '0'	Matthew Musikanth (b) (4)	05 Nov 2020 23:14:28

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 15:08:42
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:55
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 23:53:16
User entered 'No (N)'	Matthew Musikanth (b) (4)	05 Nov 2020 23:14:28

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 15:08:42
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:55
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 23:53:16
User entered '18 Oct 2020'	Matthew Musikanth (b) (4)	05 Nov 2020 23:14:28

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 15:08:42
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:55
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 23:53:16
User entered 'No (N)'	Matthew Musikanth (b) (4)	05 Nov 2020 23:14:28

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 15:08:42
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:55
User entered empty.	System	05 Nov 2020 23:14:28

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 15:08:42
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:55
User entered empty.	System	05 Nov 2020 23:14:28

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 15:08:42
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:13:55
User entered empty.	System	05 Nov 2020 23:14:28

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 15:08:42
Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL 3350, PRODUCTSYNONYM: MIRALAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 21:24:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 21:24:12
Data point term sent to Coder	System	12 Apr 2021 20:46:03
Coding entries removed.	Matthew Musikanth (b) (4)	12 Apr 2021 20:45:14
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL 3350, PRODUCTSYNONYM: MIRALAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 21:34:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 21:34:40
Data point term sent to Coder	System	10 Nov 2020 21:34:07
User entered 'miralax'	Natalie Moy (b) (4) (b) (4)	10 Nov 2020 21:33:24

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 15:08:42
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'No (N)'	Natalie Moy (b) (4) (b) (4)	10 Nov 2020 21:33:24

FDA-CBER-2022-1614-0510562

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 15:08:42
Indication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	15 Apr 2021 23:36:03
Signature has been broken.	Matthew Musikanth (b) (4)	12 Apr 2021 20:45:14
User entered 'Hiatal Hernia' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	12 Apr 2021 20:45:14
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'colon polyps'	Natalie Moy (b) (4) (b) (4)	10 Nov 2020 21:33:24

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 15:08:42
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered '1'	Natalie Moy (b) (4) (b) (4)	10 Nov 2020 21:33:24

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 15:08:42
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'capsule (CAPSULE)'	Natalie Moy (b) (4) (b) (4)	10 Nov 2020 21:33:24

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 15:08:42
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Natalie Moy (b) (4) (b) (4)	10 Nov 2020 21:33:24

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 15:08:42
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'as needed (PRN)'	Natalie Moy (b) (4) (b) (4)	10 Nov 2020 21:33:24

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 15:08:42
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Natalie Moy (b) (4) (b) (4)	10 Nov 2020 21:33:24

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 15:08:42
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'Oral (ORAL)'	Natalie Moy (b) (4) (b) (4)	10 Nov 2020 21:33:24

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 15:08:42
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Natalie Moy (b) (4) (b) (4)	10 Nov 2020 21:33:24

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 15:08:42
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	15 Apr 2021 23:36:03
Signature has been broken.	Matthew Musikanth (b) (4)	12 Apr 2021 20:45:14
User entered 'UN UNK 2019' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	12 Apr 2021 20:45:14
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'un UNK 2017'	Natalie Moy (b) (4) (b) (4)	10 Nov 2020 21:33:24

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 15:08:42
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered '0'	Natalie Moy (b) (4) (b) (4)	10 Nov 2020 21:33:24

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 15:08:42
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'Yes (Y)'	Natalie Moy (b) (4) (b) (4)	10 Nov 2020 21:33:24

FDA-CBER-2022-1614-0510573

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 15:08:42
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Natalie Moy (b) (4) (b) (4)	10 Nov 2020 21:33:24

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 15:08:42
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'No (N)'	Natalie Moy (b) (4) (b) (4)	10 Nov 2020 21:33:24

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 15:08:42
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 21:33:24

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 15:08:42
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 21:33:24

US3112192
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 15:08:42
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 21:33:24

US3112192
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Generated On: 09 Jun 2021 15:08:42
Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:44:57
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'Yes (Y)' reason for change: New Information	Brenda Grande (b) (4) (b) (4)	10 Mar 2021 22:16:13
User entered 'No (N)' reason for change: Data Entry Error	Brenda Grande (b) (4) (b) (4)	15 Jan 2021 00:01:31
User entered 'Yes (Y)'	Nicolle Mendez (b) (4) (b) (4)	18 Sep 2020 19:58:57

US3112192
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (4)
Generated On: 09 Jun 2021 15:08:42
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered '23 Feb 2021'	Brenda Grande (b) (4) (b) (4)	10 Mar 2021 22:16:02

US3112192
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (4)
Generated On: 09 Jun 2021 15:08:42
Procedure/Surgery

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'heart ablation'	Brenda Grande (b) (4) (b) (4)	10 Mar 2021 22:16:02

FDA-CBER-2022-1614-0510581

US3112192
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (4)
Generated On: 09 Jun 2021 15:08:42
Indication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered 'Adverse Event (AE)'	Brenda Grande (b) (4) (b) (4)	10 Mar 2021 22:16:02

US3112192
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (4)
Generated On: 09 Jun 2021 15:08:42
If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:12:53
User entered empty.	Brenda Grande (b) (4) (b) (4)	10 Mar 2021 22:16:02

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:43
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'USA-US062-2020-MRNA-1273-P301000006'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Serious

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:45
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'Yes (Y)'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Death

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:46
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'No (N)'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:48
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'No (N)'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:50
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'Yes (Y)'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:52
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'No (N)'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:54
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'No (N)'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'No (N)'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'Laurie'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'Han-Conrad'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:55:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered '9040 Friars Rd St 540'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:55:03
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'San Diego'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:55:05
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'CA'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:55:07
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered '92108'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 19:58:24
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:55:09
User entered 'US'	System	23 Oct 2020 21:15:04

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '5'	System	19 Nov 2020 13:14:34
User entered '4'	System	18 Nov 2020 18:15:35
User entered '3'	System	06 Nov 2020 13:16:13
User entered '2'	System	03 Nov 2020 19:58:38
User entered '1'	System	23 Oct 2020 21:15:04

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:43
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'USA-US062-2020-MRNA-1273-P301000006'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Serious

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:45
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'Yes (Y)'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Death

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:46
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'No (N)'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:48
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'No (N)'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:50
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'Yes (Y)'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:52
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'No (N)'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:54
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'No (N)'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'No (N)'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'Laurie'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'Han-Conrad'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:55:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered '9040 Friars Rd St 540'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:55:03
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'San Diego'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:55:05
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'CA'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:55:07
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered '92108'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 19:58:24
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:55:09
User entered 'US'	System	23 Oct 2020 21:15:04

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '5'	System	19 Nov 2020 13:14:34
User entered '4'	System	18 Nov 2020 18:15:35
User entered '3'	System	06 Nov 2020 13:16:13
User entered '2'	System	03 Nov 2020 19:58:38
User entered '1'	System	23 Oct 2020 21:15:04

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form (1)
Generated On: 09 Jun 2021 15:08:42
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:22:00
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '23/Oct/2020 17:15'	System	23 Oct 2020 21:15:04

US3112192

Folder: SAE USA-US062-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:08:42

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:22:00
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 19:58:24
User entered '1'	(b) (4), (b) (6)	23 Oct 2020 21:15:04

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:43
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'USA-US062-2020-MRNA-1273-P301000006'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Serious

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:45
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'Yes (Y)'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Death

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:46
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'No (N)'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:48
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'No (N)'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:50
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'Yes (Y)'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:52
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'No (N)'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:54
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'No (N)'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'No (N)'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'Laurie'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'Han-Conrad'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:55:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered '9040 Friars Rd St 540'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:55:03
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'San Diego'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:55:05
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'CA'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:55:07
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered '92108'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 19:58:24
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:55:09
User entered 'US'	System	23 Oct 2020 21:15:04

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '5'	System	19 Nov 2020 13:14:34
User entered '4'	System	18 Nov 2020 18:15:35
User entered '3'	System	06 Nov 2020 13:16:13
User entered '2'	System	03 Nov 2020 19:58:38
User entered '1'	System	23 Oct 2020 21:15:04

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form (2)
Generated On: 09 Jun 2021 15:08:42
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:22:00
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '03/Nov/2020 19:58'	System	03 Nov 2020 19:58:38

US3112192

Folder: SAE USA-US062-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:08:42

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:22:00
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 13:16:03
User entered '1'	(b) (4), (b) (6)	03 Nov 2020 19:58:38

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:43
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'USA-US062-2020-MRNA-1273-P301000006'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Serious

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:45
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'Yes (Y)'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Death

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:46
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'No (N)'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:48
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'No (N)'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:50
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'Yes (Y)'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:52
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'No (N)'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:54
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'No (N)'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'No (N)'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'Laurie'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'Han-Conrad'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:55:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered '9040 Friars Rd St 540'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:55:03
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'San Diego'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:55:05
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'CA'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:55:07
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered '92108'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 19:58:24
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:55:09
User entered 'US'	System	23 Oct 2020 21:15:04

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '5'	System	19 Nov 2020 13:14:34
User entered '4'	System	18 Nov 2020 18:15:35
User entered '3'	System	06 Nov 2020 13:16:13
User entered '2'	System	03 Nov 2020 19:58:38
User entered '1'	System	23 Oct 2020 21:15:04

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form (3)
Generated On: 09 Jun 2021 15:08:42
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:22:00
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '06/Nov/2020 13:16'	System	06 Nov 2020 13:16:13

US3112192

Folder: SAE USA-US062-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:08:42

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:22:00
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 18:15:24
User entered '1'	(b) (4), (b) (6)	06 Nov 2020 13:16:13

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:43
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'USA-US062-2020-MRNA-1273-P301000006'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Serious

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:45
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'Yes (Y)'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Death

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:46
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'No (N)'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:48
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'No (N)'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:50
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'Yes (Y)'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:52
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'No (N)'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:54
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'No (N)'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'No (N)'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'Laurie'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'Han-Conrad'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:55:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered '9040 Friars Rd St 540'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:55:03
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'San Diego'	System	23 Oct 2020 21:14:34

FDA-CBER-2022-1614-0510665

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:55:05
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'CA'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:55:07
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered '92108'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 19:58:24
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:55:09
User entered 'US'	System	23 Oct 2020 21:15:04

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '5'	System	19 Nov 2020 13:14:34
User entered '4'	System	18 Nov 2020 18:15:35
User entered '3'	System	06 Nov 2020 13:16:13
User entered '2'	System	03 Nov 2020 19:58:38
User entered '1'	System	23 Oct 2020 21:15:04

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form (4)
Generated On: 09 Jun 2021 15:08:42
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:22:00
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '18/Nov/2020 18:15'	System	18 Nov 2020 18:15:35

US3112192

Folder: SAE USA-US062-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:08:42

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:22:00
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 13:14:19
User entered '1'	(b) (4), (b) (6)	18 Nov 2020 18:15:35

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:43
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'USA-US062-2020-MRNA-1273-P301000006'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Serious

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:45
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'Yes (Y)'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Death

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:46
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'No (N)'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:48
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'No (N)'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:50
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'Yes (Y)'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:52
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'No (N)'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:54
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'No (N)'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:56
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'No (N)'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'Laurie'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:54:59
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'Han-Conrad'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:55:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered '9040 Friars Rd St 540'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:55:03
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'San Diego'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:55:05
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered 'CA'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:55:07
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 21:14:56
User entered '92108'	System	23 Oct 2020 21:14:34

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 19:58:24
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 17:55:09
User entered 'US'	System	23 Oct 2020 21:15:04

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 09 Jun 2021 15:08:42
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '5'	System	19 Nov 2020 13:14:34
User entered '4'	System	18 Nov 2020 18:15:35
User entered '3'	System	06 Nov 2020 13:16:13
User entered '2'	System	03 Nov 2020 19:58:38
User entered '1'	System	23 Oct 2020 21:15:04

US3112192
Folder: SAE USA-US062-2020-MRNA-1273-P301000006
Form: Safety Report Form (5)
Generated On: 09 Jun 2021 15:08:42
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:22:00
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '19/Nov/2020 08:14'	System	19 Nov 2020 13:14:34

US3112192

Folder: SAE USA-US062-2020-MRNA-1273-P301000006

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:08:42

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:22:00
User signature succeeded.	Todd Simmons (b) (4) (b) (4)	02 Apr 2021 21:13:15
User entered '1'	(b) (4), (b) (6)	19 Nov 2020 13:14:34