US3662116 (Prod: Cincinnati CRS)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:24:58

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US3662116
Form: Participant Creation
Data signed: (b) (4) **18 Mar 2021 22:08:20**
Generated On: 10 Jun 2021 09:24:58

Participant ID	US3662116

mRNA-1273-P301 Completion Guidelines

FDA-CBER-2022-1614-2918236

US3662116
Folder: Screening
Form: Visit Date
Data signed: (b) (4) **18 Mar 2021 22:08:23**
Generated On: 10 Jun 2021 09:24:58

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	18 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	SCRN

FDA-CBER-2022-1614-2918237

US3662116
Folder: Screening
Form: Demographics
Data signed: (b) (4) **18 Mar 2021 22:08:23**
Generated On: 10 Jun 2021 09:24:58

Date of Birth (MMM yyyy)	(b) (6) 1965
Age	54
Age Units	YEARS
Age (Derived)	54
Sex	Female ■ Male ☐
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ■ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	False
Black	True
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-2022-1614-2918238

US3662116
Folder: Screening
Form: Enrollment
Data signed: (b) (4) **18 Mar 2021 22:08:23**
Generated On: 10 Jun 2021 09:24:58

Date of Informed Consent *(dd MMM yyyy)*	18 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☐ Amendment 2 ☐ Amendment 3 ■ Amendment 4 ☐ Amendment 5 ☐
Was participant enrolled in the study?	Yes ■ No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐ Inclusion/Exclusion ☐ Cohort Full ☐ Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐ No ■
If Yes, previous participant number	
Enrollment Trigger	1

FDA-CBER-2022-1614-2918239

US3662116
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Data signed: (b) (4) **18 Mar 2021 22:08:23**
Generated On: 10 Jun 2021 09:24:58

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

FDA-CBER-2022-1614-2918240

US3662116
Folder: Screening
Form: Medical History Summary
Data signed: (b) (4) **18 Mar 2021 22:08:23**
Generated On: 10 Jun 2021 09:24:58

Were any significant conditions reported?	Yes ■ No ☐

FDA-CBER-2022-1614-2918241

US3662116
Folder: Screening
Form: Medical History (1)
Data signed: (b) (4) **16 Apr 2021 19:05:54**
Generated On: 10 Jun 2021 09:24:58

Condition	EXOSTOSIS - BONE SPUR LEFT KNEE
Start date (dd MMM yyyy)	07 JUL 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)	JUL 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-2918242

US3662116
Folder: Screening
Form: Medical History (2)
Data signed: (b) (4) **16 Apr 2021 19:05:54**
Generated On: 10 Jun 2021 09:24:58

Condition	LEFT KNEE PAIN
Start date (dd MMM yyyy)	01 JUL 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)	JUL 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-2918243

US3662116
Folder: Screening
Form: Medical History (3)
Data signed: (b) (4) **16 Apr 2021 19:05:54**
Generated On: 10 Jun 2021 09:24:58

Condition	MORBID OBESITY
Start date (dd MMM yyyy)	08 JUL 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-2918244

US3662116
Folder: Screening
Form: Medical History (4)
Data signed: (b) (4) **16 Apr 2021 19:05:54**
Generated On: 10 Jun 2021 09:24:58

Condition	HYPERTENSION NEC
Start date (dd MMM yyyy)	01 JUL 2001
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)	JUL 2001
Start Year (derived)	2001
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-2918245

US3662116
Folder: Screening
Form: Medical History (5)
Data signed: (b) (4) **16 Apr 2021 19:05:54**
Generated On: 10 Jun 2021 09:24:58

Condition	COMPLETE ABDOMINAL HYSTERECTOMY
Start date (dd MMM yyyy)	31 MAY 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ■
If No, please specify the stop date (dd MMM yyyy)	31 MAY 2018
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2018
Start Year (derived)	2018
Stop Month and Year (derived)	MAY 2018
Stop Year (derived)	2018

FDA-CBER-2022-1614-2918246

US3662116
Folder: Screening
Form: Medical History (6)
Data signed: (b) (4) **16 Apr 2021 19:05:54**
Generated On: 10 Jun 2021 09:24:58

Condition	ADENEXAL MASS
Start date (dd MMM yyyy)	15 DEC 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☑
If No, please specify the stop date (dd MMM yyyy)	31 MAY 2018
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2017
Start Year (derived)	2017
Stop Month and Year (derived)	MAY 2018
Stop Year (derived)	2018

FDA-CBER-2022-1614-2918247

US3662116
Folder: Screening
Form: Medical History (7)
Data signed: (b) (4) **16 Apr 2021 19:05:54**
Generated On: 10 Jun 2021 09:24:58

Condition	CHRONIC GENERALIZED PAIN
Start date (dd MMM yyyy)	1 NOV 2019
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)	NOV 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-2918248

US3662116
Folder: Screening
Form: Medical History (8)
Data signed: (b) (4) **16 Apr 2021 19:05:54**
Generated On: 10 Jun 2021 09:24:58

Condition	GASTRO-ESOPHAGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	22 MAR 2019
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)	MAR 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-2918249

US3662116
Folder: Screening
Form: Medical History (9)
Data signed: (b) (4) **16 Apr 2021 19:05:54**
Generated On: 10 Jun 2021 09:24:58

Condition	INFRA-RENAL AORTIC DISSECTION
Start date (dd MMM yyyy)	1 APR 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes ■ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	APR 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-2918250

US3662116
Folder: Screening
Form: Medical History (10)
Data signed: (b) (4) **16 Apr 2021 19:05:54**
Generated On: 10 Jun 2021 09:24:58

Condition	MALIGNANT NEOPLASM OF GALLBLADDER
Start date (dd MMM yyyy)	10 APR 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ■
If No, please specify the stop date (dd MMM yyyy)	03 FEB 2015
Stop date completely unknown	False
Start Month and Year (derived)	APR 2014
Start Year (derived)	2014
Stop Month and Year (derived)	FEB 2015
Stop Year (derived)	2015

FDA-CBER-2022-1614-2918251

US3662116
Folder: Screening
Form: Medical History (11)
Data signed: (b) (4) **16 Apr 2021 19:05:54**
Generated On: 10 Jun 2021 09:24:58

Condition	PULMONARY EMBOLISM ACUTE
Start date (dd MMM yyyy)	11 MAY 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ■
If No, please specify the stop date (dd MMM yyyy)	9 MAY 2018
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2017
Start Year (derived)	2017
Stop Month and Year (derived)	MAY 2018
Stop Year (derived)	2018

FDA-CBER-2022-1614-2918252

US3662116
Folder: Screening
Form: Medical History (12)
Data signed: (b) (4) **16 Apr 2021 19:05:54**
Generated On: 10 Jun 2021 09:24:58

Condition	INCISIONAL HERNIA WITHOUT OBSTRUCTION OR GANGRENE
Start date (dd MMM yyyy)	13 MAR 2015
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)	MAR 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

US3662116
Folder: Screening
Form: Medical History (13)
Data signed: (b) (4) **16 Apr 2021 19:05:54**
Generated On: 10 Jun 2021 09:24:58

Condition	CHOLECYSTECTOMY WITH PARTIAL HEPATECTOMY
Start date (dd MMM yyyy)	09 MAY 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ■
If No, please specify the stop date (dd MMM yyyy)	09 MAY 2014
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2014
Start Year (derived)	2014
Stop Month and Year (derived)	MAY 2014
Stop Year (derived)	2014

FDA-CBER-2022-1614-2918254

US3662116
Folder: Screening
Form: Medical History (14)
Data signed: (b) (4) **16 Apr 2021 19:05:54**
Generated On: 10 Jun 2021 09:24:58

Condition	HERPES SIMPLEX VIRUS 2
Start date (dd MMM yyyy)	11 JAN 2019
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 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-2918255

US3662116
Folder: Screening
Form: Medical History (15)
Data signed: (b) (4) **16 Apr 2021 19:05:54**
Generated On: 10 Jun 2021 09:24:58

Condition	ANXIETY STATE UNSPECIFIED
Start date (dd MMM yyyy)	25 JAN 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-2022-1614-2918256

US3662116
Folder: Screening
Form: Medical History (16)
Data signed: (b) (4) **16 Apr 2021 19:05:54**
Generated On: 10 Jun 2021 09:24:58

Condition	INSOMNIA
Start date (dd MMM yyyy)	25 JAN 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-2022-1614-2918257

US3662116
Folder: Screening
Form: Vital Signs
Data signed: (b) (4) **18 Mar 2021 22:08:23**
Generated On: 10 Jun 2021 09:24:58

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	18 SEP 2020
Time of assessment *(00:00-23:59)*	08:48 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 08:48
Height *(xxx.x)*	153 cm
Weight *(xxx.x)*	119.3 kg
BMI *(xxx.x)*	50.96330 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)	

US3662116
Folder: Screening
Form: Physical Examination
Data signed: (b) (4) **18 Mar 2021 22:08:23**
Generated On: 10 Jun 2021 09:24:58

Was the physical examination performed?	Yes ☑ No ☐
Date of examination *(dd MMM yyyy)*	18 SEP 2020

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

FDA-CBER-2022-1614-2918259

US3662116
Folder: Screening
Form: Childbearing Potential
Data signed: (b) (4) **18 Mar 2021 22:08:23**
Generated On: 10 Jun 2021 09:24:58

Date of assessment *(dd MMM yyyy)*	18 SEP 2020
Is the participant of childbearing potential?	Yes ☐
	No ■
If No, what is the reason?	Surgically sterile ■
	Post-menopausal ☐
	Partner medically sterile ☐
	Not reached age of Menarche ☐
	Other ☐
If Partner medically sterile or Other, specify	
If Surgically sterile, date of surgery *(dd MMM yyyy)*	31 MAY 2018
Date of surgery unknown	False
If Post-menopausal, date of last menstruation *(dd MMM yyyy)*	
Date of last menstruation unknown	False

FDA-CBER-2022-1614-2918260

US3662116
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **18 Mar 2021 22:08:23**
Generated On: 10 Jun 2021 09:24:58

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-2022-1614-2918261

US3662116
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **18 Mar 2021 22:08:23**
Generated On: 10 Jun 2021 09:24:58

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)	True
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

FDA-CBER-2022-1614-2918262

US3662116
Folder: Visit 1 Day 1
Form: Visit Date
Data signed: (b) (4) **18 Mar 2021 22:08:23**
Generated On: 10 Jun 2021 09:24:58

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	18 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT1

FDA-CBER-2022-1614-2918263

US3662116
Folder: Visit 1 Day 1
Form: Randomization
Data signed: (b) (4) **18 Mar 2021 22:08:23**
Generated On: 10 Jun 2021 09:24:58

What was the date of randomization? *(dd MMM yyyy)*	18 SEP 2020
What was the participant's randomization number?	146331
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-2022-1614-2918264

US3662116
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Data signed: (b) (4) **18 Mar 2021 22:08:23**
Generated On: 10 Jun 2021 09:24:58

Height	ND - Not Done
Weight	ND - Not Done

FDA-CBER-2022-1614-2918265

US3662116
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **18 Mar 2021 22:08:23**
Generated On: 10 Jun 2021 09:24:58

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)*	18 SEP 2020
Time of assessment *(00:00-23:59)*	08:48 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 08:48
Temperature *(xxx.x)*	97.3 F
Route of measurement	Oral ☐ Axillary ☐ Other ■
If Other, specify	INFRARED THERMOMETER
Pulse *(xxx)*	93 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	83 mmHg
Diastolic Blood Pressure units	MMHG

US3662116
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **18 Mar 2021 22:08:23**
Generated On: 10 Jun 2021 09:24:58

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)*	18 SEP 2020
Time of assessment *(00:00-23:59)*	10:48 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 10:48
Temperature *(xxx.x)*	98.0 F
Route of measurement	Oral ☐ Axillary ☐ Other ■
If Other, specify	INFRARED THERMOMETER
Pulse *(xxx)*	91 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	81 mmHg
Diastolic Blood Pressure units	MMHG

US3662116
Folder: Visit 1 Day 1
Form: Physical Examination
Data signed: (b) (4) **18 Mar 2021 22:08:23**
Generated On: 10 Jun 2021 09:24:58

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

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

FDA-CBER-2022-1614-2918268

US3662116
Folder: Visit 1 Day 1
Form: Exposure
Data signed: (b) (4) **18 Mar 2021 22:08:23**
Generated On: 10 Jun 2021 09:24:58

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)*	18 SEP 2020
What was the treatment time? *(00:00-23:59)*	10:17 (24 HR)
Treatment Date and Time (derived)	18 SEP 2020 10:17
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

US3662116
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Data signed: (b) (4) **18 Mar 2021 22:08:23**
Generated On: 10 Jun 2021 09:24:58

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	18 SEP 2020
Collection time *(00:00-23:59)*	09:25 (24 HR)
Collection date and time (derived)	18 SEP 2020 09:25

FDA-CBER-2022-1614-2918270

US3662116
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **18 Mar 2021 22:08:23**
Generated On: 10 Jun 2021 09:24:58

Collection date *(dd MMM yyyy)*			18 SEP 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:20	18 SEP 2020 09:20
Nasopharyngeal Swab 2	No		

FDA-CBER-2022-1614-2918271

US3662116
Folder: Visit 1 Day 1
Form: Continuing
Data signed: (b) (4) **18 Mar 2021 22:08:23**
Generated On: 10 Jun 2021 09:24:58

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

FDA-CBER-2022-1614-2918272

US3662116
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:24:58

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.0 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	18 SEP 2020 10:49
PC Open Date & Time	18 SEP 2020 10:37
PC Close Date & Time	18 SEP 2020 13:07

FDA-CBER-2022-1614-2918273

US3662116
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:24:58

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**	98.0 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	18 SEP 2020 17:10
PC Open Date & Time	18 SEP 2020 14:02
PC Close Date & Time	19 SEP 2020 11:59

FDA-CBER-2022-1614-2918274

US3662116
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:24:58

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**	98.2 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	19 SEP 2020 17:04
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

FDA-CBER-2022-1614-2918275

US3662116
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:24:58

TIMEPOINT	DAY 3

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.2 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	20 SEP 2020 12:24
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3662116
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:24:58

TIMEPOINT	DAY 4

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.0 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	21 SEP 2020 17:30
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

FDA-CBER-2022-1614-2918277

US3662116
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:24:58

TIMEPOINT	DAY 5

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.0 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	22 SEP 2020 16:35
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

FDA-CBER-2022-1614-2918278

US3662116
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:24:58

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**	98.2 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	23 SEP 2020 16:03
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3662116
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:24:58

TIMEPOINT	DAY 7

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.9 °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	24 SEP 2020 13:39
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:24:58

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	18 SEP 2020 10:48
PC Open Date & Time	18 SEP 2020 10:37
PC Close Date & Time	18 SEP 2020 13:07

FDA-CBER-2022-1614-2918281

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:24:58

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	18 SEP 2020 17:09
PC Open Date & Time	18 SEP 2020 14:02
PC Close Date & Time	19 SEP 2020 11:59

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:24:58

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	19 SEP 2020 17:04
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:24:58

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	20 SEP 2020 12:25
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:24:58

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	21 SEP 2020 17:30
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:24:58

TIMEPOINT	DAY 5
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	22 SEP 2020 23:13
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:24:58

TIMEPOINT	DAY 6
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	23 SEP 2020 16:04
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:24:58

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	24 SEP 2020 13:39
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 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-2022-1614-2918289

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:24:58

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	18 SEP 2020 10:49
PC Open Date & Time	18 SEP 2020 10:37
PC Close Date & Time	18 SEP 2020 13:07

FDA-CBER-2022-1614-2918290

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-2022-1614-2918291

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:24:58

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	18 SEP 2020 17:11
PC Open Date & Time	18 SEP 2020 14:02
PC Close Date & Time	19 SEP 2020 11:59

FDA-CBER-2022-1614-2918292

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:24:58

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-2022-1614-2918293

	Yes ☐
PC Time stamp	19 SEP 2020 17:05
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:24:58

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-2022-1614-2918295

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:24:58

	Yes ☐
PC Time stamp	20 SEP 2020 12:26
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:24:58

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-2022-1614-2918297

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:24:58

	Yes ☐
PC Time stamp	21 SEP 2020 17:31
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

FDA-CBER-2022-1614-2918298

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:24:58

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-2022-1614-2918299

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:24:58

	Yes ☐
PC Time stamp	22 SEP 2020 23:13
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:24:58

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-2022-1614-2918301

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:24:58

	Yes ☐
PC Time stamp	23 SEP 2020 16:04
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:24:58

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-2022-1614-2918303

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:24:58

	Yes ☐
PC Time stamp	24 SEP 2020 13:40
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

FDA-CBER-2022-1614-2918304

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Pain_Day(8)
Generated On: 10 Jun 2021 09:24:58

TIMEPOINT	DAY 8
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 ☐
PC Time Stamp	25 SEP 2020 12:19
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

FDA-CBER-2022-1614-2918305

US3662116
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 10 Jun 2021 09:24:58

TIMEPOINT	DAY 8
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	25 SEP 2020 12:19
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

FDA-CBER-2022-1614-2918306

US3662116
Folder: Safety Call Day 8 (1)
Form: Safety Call
Data signed: (b) (4) **18 Mar 2021 22:08:23**
Generated On: 10 Jun 2021 09:24:58

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-2022-1614-2918307

US3662116
Folder: Safety Call Day 8 (1)
Form: Continuing
Data signed: (b) (4) **18 Mar 2021 22:08:23**
Generated On: 10 Jun 2021 09:24:58

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

FDA-CBER-2022-1614-2918308

US3662116
Folder: Safety Call Day 15 (1)
Form: Safety Call
Data signed: (b) (4) **18 Mar 2021 22:08:22**
Generated On: 10 Jun 2021 09:24:58

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	02 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-2022-1614-2918309

US3662116
Folder: Safety Call Day 15 (1)
Form: Continuing
Data signed: (b) (4) **18 Mar 2021 22:08:22**
Generated On: 10 Jun 2021 09:24:58

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

FDA-CBER-2022-1614-2918310

US3662116
Folder: Safety Call Day 22 (1)
Form: Safety Call
Data signed: (b) (4) **18 Mar 2021 22:08:22**
Generated On: 10 Jun 2021 09:24:58

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	09 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-2022-1614-2918311

US3662116
Folder: Safety Call Day 22 (1)
Form: Continuing
Data signed: (b) (4) **18 Mar 2021 22:08:22**
Generated On: 10 Jun 2021 09:24:58

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

FDA-CBER-2022-1614-2918312

US3662116
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Data signed: (b) (4) **18 Mar 2021 22:08:23**
Generated On: 10 Jun 2021 09:24:58

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	16 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT2

FDA-CBER-2022-1614-2918313

US3662116
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **18 Mar 2021 22:08:23**
Generated On: 10 Jun 2021 09:24:58

Timepoint	Pre-Dose ■ Post-Dose ☐
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	16 OCT 2020
Time of assessment *(00:00-23:59)*	09:43 (24 HR)
Vital Signs Date and Time (derived)	16 OCT 2020 09:43
Temperature *(xxx.x)*	97.6 F
Route of measurement	Oral ☐ Axillary ☐ Other ■
If Other, specify	INFRARED THERMOMETER
Pulse *(xxx)*	96 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)*	87 mmHg
Diastolic Blood Pressure units	MMHG

US3662116
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **18 Mar 2021 22:08:23**
Generated On: 10 Jun 2021 09:24:58

Timepoint	Pre-Dose ☐ Post-Dose ■
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	16 OCT 2020
Time of assessment *(00:00-23:59)*	11:05 (24 HR)
Vital Signs Date and Time (derived)	16 OCT 2020 11:05
Temperature *(xxx.x)*	97.3 F
Route of measurement	Oral ☐ Axillary ☐ Other ■
If Other, specify	INFRARED THERMOMETER
Pulse *(xxx)*	94 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	89 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-2918315

US3662116
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Data signed: (b) (4) **18 Mar 2021 22:08:23**
Generated On: 10 Jun 2021 09:24:58

Was the physical examination performed?	Yes ☑ No ☐
Date of examination *(dd MMM yyyy)*	16 OCT 2020

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

FDA-CBER-2022-1614-2918316

US3662116
Folder: Visit 2 Day 29 (1)
Form: Exposure
Data signed: (b) (4) **18 Mar 2021 22:08:23**
Generated On: 10 Jun 2021 09:24:58

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)*	16 OCT 2020
What was the treatment time? *(00:00-23:59)*	10:35 (24 HR)
Treatment Date and Time (derived)	16 OCT 2020 10:35
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-2022-1614-2918317

US3662116
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **18 Mar 2021 22:08:23**
Generated On: 10 Jun 2021 09:24:58

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	16 OCT 2020
Collection time *(00:00-23:59)*	09:55 (24 HR)
Collection date and time (derived)	16 OCT 2020 09:55

FDA-CBER-2022-1614-2918318

US3662116
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **18 Mar 2021 22:08:23**
Generated On: 10 Jun 2021 09:24:58

Collection date *(dd MMM yyyy)*			16 OCT 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:50	16 OCT 2020 09:50
Nasopharyngeal Swab 2	No		

FDA-CBER-2022-1614-2918319

US3662116
Folder: Visit 2 Day 29 (1)
Form: Continuing
Data signed: (b) (4) **18 Mar 2021 22:08:23**
Generated On: 10 Jun 2021 09:24:58

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

FDA-CBER-2022-1614-2918320

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:24:58

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.3 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	16 OCT 2020 11:07
PC Open Date & Time	16 OCT 2020 10:55
PC Close Date & Time	16 OCT 2020 13:25

FDA-CBER-2022-1614-2918321

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:24:58

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.9 °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	16 OCT 2020 17:16
PC Open Date & Time	16 OCT 2020 14:20
PC Close Date & Time	17 OCT 2020 11:59

FDA-CBER-2022-1614-2918322

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:24:58

TIMEPOINT	DAY 2

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	99.2 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ■ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	True
To **PREVENT** pain or fever from occurring	False
PC Time Stamp	17 OCT 2020 13:07
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

FDA-CBER-2022-1614-2918323

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:24:58

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):	
PC Time Stamp	18 OCT 2020 15:32
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:24:58

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**	99.1 °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	19 OCT 2020 18:37
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:24:58

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**	97.6 °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	20 OCT 2020 15:10
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:24:58

TIMEPOINT	DAY 6

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.7 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	21 OCT 2020 14:32
PC Open Date & Time	21 OCT 2020 12:00
PC Close Date & Time	22 OCT 2020 11:59

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:24:58

TIMEPOINT	DAY 7

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.2 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	22 OCT 2020 12:09
PC Open Date & Time	22 OCT 2020 12:00
PC Close Date & Time	23 OCT 2020 11:59

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:24:58

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	16 OCT 2020 11:07
PC Open Date & Time	16 OCT 2020 10:55
PC Close Date & Time	16 OCT 2020 13:25

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:24:58

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	16 OCT 2020 17:17
PC Open Date & Time	16 OCT 2020 14:20
PC Close Date & Time	17 OCT 2020 11:59

FDA-CBER-2022-1614-2918330

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:24:58

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	17 OCT 2020 13:08
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:24:58

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	18 OCT 2020 15:32
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:24:58

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	19 OCT 2020 18:37
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:24:58

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	20 OCT 2020 15:11
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:24:58

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	21 OCT 2020 14:33
PC Open Date & Time	21 OCT 2020 12:00
PC Close Date & Time	22 OCT 2020 11:59

FDA-CBER-2022-1614-2918335

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:24:58

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	22 OCT 2020 12:09
PC Open Date & Time	22 OCT 2020 12:00
PC Close Date & Time	23 OCT 2020 11:59

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

FDA-CBER-2022-1614-2918337

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:24:58

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	16 OCT 2020 11:08
PC Open Date & Time	16 OCT 2020 10:55
PC Close Date & Time	16 OCT 2020 13:25

FDA-CBER-2022-1614-2918338

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

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:24:58

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	16 OCT 2020 17:17
PC Open Date & Time	16 OCT 2020 14:20
PC Close Date & Time	17 OCT 2020 11:59

FDA-CBER-2022-1614-2918340

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:24:58

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-2022-1614-2918341

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:24:58

	Yes ☐
PC Time stamp	17 OCT 2020 13:08
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:24:58

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-2022-1614-2918343

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:24:58

	Yes ☐
PC Time stamp	18 OCT 2020 15:33
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

FDA-CBER-2022-1614-2918344

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:24:58

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-2022-1614-2918345

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:24:58

	Yes ☐
PC Time stamp	19 OCT 2020 18:38
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

FDA-CBER-2022-1614-2918346

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:24:58

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-2022-1614-2918347

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:24:58

	Yes ☐
PC Time stamp	20 OCT 2020 15:11
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:24:58

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-2022-1614-2918349

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:24:58

	Yes ☐
PC Time stamp	21 OCT 2020 14:33
PC Open Date & Time	21 OCT 2020 12:00
PC Close Date & Time	22 OCT 2020 11:59

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:24:58

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-2022-1614-2918351

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:24:58

	Yes ☐
PC Time stamp	22 OCT 2020 12:10
PC Open Date & Time	22 OCT 2020 12:00
PC Close Date & Time	23 OCT 2020 11:59

US3662116
Folder: Safety Call Day 36 (1)
Form: Safety Call
Data signed: (b) (4) **18 Mar 2021 22:08:22**
Generated On: 10 Jun 2021 09:24:58

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	23 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-2022-1614-2918353

US3662116
Folder: Safety Call Day 36 (1)
Form: Continuing
Data signed: (b) (4) **18 Mar 2021 22:08:22**
Generated On: 10 Jun 2021 09:24:58

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

FDA-CBER-2022-1614-2918354

US3662116
Folder: Safety Call Day 43 (1)
Form: Safety Call
Data signed: (b) (4) **18 Mar 2021 22:08:22**
Generated On: 10 Jun 2021 09:24:58

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	30 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-2022-1614-2918355

US3662116
Folder: Safety Call Day 43 (1)
Form: Continuing
Data signed: (b) (4) **18 Mar 2021 22:08:22**
Generated On: 10 Jun 2021 09:24:58

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

FDA-CBER-2022-1614-2918356

US3662116
Folder: Safety Call Day 50 (1)
Form: Safety Call
Data signed: (b) (4) **18 Mar 2021 22:08:22**
Generated On: 10 Jun 2021 09:24:58

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-2022-1614-2918357

US3662116
Folder: Safety Call Day 50 (1)
Form: Continuing
Data signed: (b) (4) **18 Mar 2021 22:08:22**
Generated On: 10 Jun 2021 09:24:58

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

FDA-CBER-2022-1614-2918358

US3662116
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Data signed: (b) (4) **18 Mar 2021 22:08:23**
Generated On: 10 Jun 2021 09:24:58

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	16 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT3

FDA-CBER-2022-1614-2918359

US3662116
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Data signed: (b) (4) **18 Mar 2021 22:08:23**
Generated On: 10 Jun 2021 09:24:58

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	16 NOV 2020
Time of assessment *(00:00-23:59)*	11:15 (24 HR)
Vital Signs Date and Time (derived)	16 NOV 2020 11:15
Temperature *(xxx.x)*	97.7 F
Route of measurement	Oral ☐ Axillary ☐ Other ■
If Other, specify	INFRARED THERMOMETER
Pulse *(xxx)*	87 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	90 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-2918360

US3662116
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Data signed: (b) (4) **18 Mar 2021 22:08:23**
Generated On: 10 Jun 2021 09:24:58

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	16 NOV 2020

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

FDA-CBER-2022-1614-2918361

US3662116
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **18 Mar 2021 22:08:23**
Generated On: 10 Jun 2021 09:24:58

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	16 NOV 2020
Collection time *(00:00-23:59)*	11:40 (24 HR)
Collection date and time (derived)	16 NOV 2020 11:40

FDA-CBER-2022-1614-2918362

US3662116
Folder: Visit 3 Day 57 (1)
Form: Continuing
Data signed: (b) (4) **18 Mar 2021 22:08:23**
Generated On: 10 Jun 2021 09:24:58

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

FDA-CBER-2022-1614-2918363

US3662116
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 NOV 2020 09:34:53
Patient Cloud Open Date & Time	18 NOV 2020 00:01
Patient Cloud Close Date & Time	22 NOV 2020 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 NOV 2020 07:48:35
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

TIMEPOINT	DAY 75
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	29 NOV 2020 11:10:10
Patient Cloud Open Date & Time	29 NOV 2020 00:01
Patient Cloud Close Date & Time	03 DEC 2020 23:59

FDA-CBER-2022-1614-2918366

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 DEC 2020 06:44:51
Patient Cloud Open Date & Time	06 DEC 2020 00:01
Patient Cloud Close Date & Time	10 DEC 2020 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 DEC 2020 10:13:09
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 DEC 2020 06:37:49
Patient Cloud Open Date & Time	20 DEC 2020 00:01
Patient Cloud Close Date & Time	24 DEC 2020 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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	27 DEC 2020 17:51:03
Patient Cloud Open Date & Time	27 DEC 2020 00:01
Patient Cloud Close Date & Time	31 DEC 2020 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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	03 JAN 2021 07:35:20
Patient Cloud Open Date & Time	03 JAN 2021 00:01
Patient Cloud Close Date & Time	07 JAN 2021 23:59

FDA-CBER-2022-1614-2918371

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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 contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ■
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 JAN 2021 12:48:53
Patient Cloud Open Date & Time	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59

FDA-CBER-2022-1614-2918372

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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	17 JAN 2021 21:23:22
Patient Cloud Open Date & Time	17 JAN 2021 00:01
Patient Cloud Close Date & Time	21 JAN 2021 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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	26 JAN 2021 20:06:38
Patient Cloud Open Date & Time	24 JAN 2021 00:01
Patient Cloud Close Date & Time	28 JAN 2021 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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	31 JAN 2021 19:06:36
Patient Cloud Open Date & Time	31 JAN 2021 00:01
Patient Cloud Close Date & Time	04 FEB 2021 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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	07 FEB 2021 21:38:03
Patient Cloud Open Date & Time	07 FEB 2021 00:01
Patient Cloud Close Date & Time	11 FEB 2021 23:59

FDA-CBER-2022-1614-2918376

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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 ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ■
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ■
Date and time of submission	15 FEB 2021 11:35:56
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

FDA-CBER-2022-1614-2918377

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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 ☐
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	21 FEB 2021 13:35:13
Patient Cloud Open Date & Time	21 FEB 2021 00:01
Patient Cloud Close Date & Time	25 FEB 2021 23:59

FDA-CBER-2022-1614-2918378

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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 contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ■
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 MAR 2021 06:25:06
Patient Cloud Open Date & Time	28 FEB 2021 00:01
Patient Cloud Close Date & Time	04 MAR 2021 23:59

FDA-CBER-2022-1614-2918379

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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	07 MAR 2021 08:39:49
Patient Cloud Open Date & Time	07 MAR 2021 00:01
Patient Cloud Close Date & Time	11 MAR 2021 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 MAR 2021 11:52:01
Patient Cloud Open Date & Time	14 MAR 2021 00:01
Patient Cloud Close Date & Time	18 MAR 2021 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 MAR 2021 09:00:46
Patient Cloud Open Date & Time	21 MAR 2021 00:01
Patient Cloud Close Date & Time	25 MAR 2021 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 MAR 2021 18:03:57
Patient Cloud Open Date & Time	28 MAR 2021 00:01
Patient Cloud Close Date & Time	01 APR 2021 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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	07 APR 2021 09:25:26
Patient Cloud Open Date & Time	04 APR 2021 00:01
Patient Cloud Close Date & Time	08 APR 2021 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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	11 APR 2021 21:40:19
Patient Cloud Open Date & Time	11 APR 2021 00:01
Patient Cloud Close Date & Time	15 APR 2021 23:59

FDA-CBER-2022-1614-2918385

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 APR 2021 14:06:42
Patient Cloud Open Date & Time	18 APR 2021 00:01
Patient Cloud Close Date & Time	22 APR 2021 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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	28 APR 2021 05:22:37
Patient Cloud Open Date & Time	25 APR 2021 00:01
Patient Cloud Close Date & Time	29 APR 2021 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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 identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 MAY 2021 09:18:51
Patient Cloud Open Date & Time	02 MAY 2021 00:01
Patient Cloud Close Date & Time	06 MAY 2021 23:59

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 contact your study clinic immediately. Click below to confirm that you have read this 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 ☐

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2021 00:01
Patient Cloud Close Date & Time	13 MAY 2021 23:59

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 ☐
Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2021 00:01
Patient Cloud Close Date & Time	20 MAY 2021 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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-2022-1614-2918393

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2021 00:01
Patient Cloud Close Date & Time	27 MAY 2021 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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 contact your study clinic immediately. Click below to confirm that you have read this 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 ☐

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2021 00:01
Patient Cloud Close Date & Time	03 JUN 2021 23:59

FDA-CBER-2022-1614-2918396

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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 contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2021 00:01
Patient Cloud Close Date & Time	10 JUN 2021 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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 ☐

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2021 00:01
Patient Cloud Close Date & Time	17 JUN 2021 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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 ☐

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

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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	27 JUN 2021 00:01
Patient Cloud Close Date & Time	01 JUL 2021 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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	04 JUL 2021 00:01
Patient Cloud Close Date & Time	08 JUL 2021 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2021 00:01
Patient Cloud Close Date & Time	15 JUL 2021 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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 ☐

FDA-CBER-2022-1614-2918409

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2021 00:01
Patient Cloud Close Date & Time	22 JUL 2021 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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 ☐

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2021 00:01
Patient Cloud Close Date & Time	29 JUL 2021 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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 ☐

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2021 00:01
Patient Cloud Close Date & Time	05 AUG 2021 23:59

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 ☐

US3662116
Folder: New Safety Follow Up Diary (1)
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Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2021 00:01
Patient Cloud Close Date & Time	12 AUG 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 ☐

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2021 00:01
Patient Cloud Close Date & Time	19 AUG 2021 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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 ☐

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2021 00:01
Patient Cloud Close Date & Time	26 AUG 2021 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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 ☐

US3662116
Folder: New Safety Follow Up Diary (1)
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Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2021 00:01
Patient Cloud Close Date & Time	02 SEP 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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01
Patient Cloud Close Date & Time	09 SEP 2021 23:59

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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01
Patient Cloud Close Date & Time	16 SEP 2021 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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 ☐

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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	26 SEP 2021 00:01
Patient Cloud Close Date & Time	30 SEP 2021 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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 ☐

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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	10 OCT 2021 00:01
Patient Cloud Close Date & Time	14 OCT 2021 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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	17 OCT 2021 00:01
Patient Cloud Close Date & Time	21 OCT 2021 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01
Patient Cloud Close Date & Time	28 OCT 2021 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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	31 OCT 2021 00:01
Patient Cloud Close Date & Time	04 NOV 2021 23:59

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 ☐

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2021 00:01
Patient Cloud Close Date & Time	11 NOV 2021 23:59

FDA-CBER-2022-1614-2918442

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	14 NOV 2021 00:01
Patient Cloud Close Date & Time	18 NOV 2021 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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	21 NOV 2021 00:01
Patient Cloud Close Date & Time	25 NOV 2021 23:59

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 ☐

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2021 00:01
Patient Cloud Close Date & Time	02 DEC 2021 23:59

FDA-CBER-2022-1614-2918448

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01
Patient Cloud Close Date & Time	09 DEC 2021 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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 ☐

FDA-CBER-2022-1614-2918451

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01
Patient Cloud Close Date & Time	16 DEC 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	19 DEC 2021 00:01
Patient Cloud Close Date & Time	23 DEC 2021 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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 ☐

FDA-CBER-2022-1614-2918455

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01
Patient Cloud Close Date & Time	30 DEC 2021 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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 ☐

FDA-CBER-2022-1614-2918457

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 00:01
Patient Cloud Close Date & Time	06 JAN 2022 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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 ☐

FDA-CBER-2022-1614-2918459

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 00:01
Patient Cloud Close Date & Time	13 JAN 2022 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	16 JAN 2022 00:01
Patient Cloud Close Date & Time	20 JAN 2022 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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	23 JAN 2022 00:01
Patient Cloud Close Date & Time	27 JAN 2022 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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 ☐

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 00:01
Patient Cloud Close Date & Time	03 FEB 2022 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2022 00:01
Patient Cloud Close Date & Time	10 FEB 2022 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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	13 FEB 2022 00:01
Patient Cloud Close Date & Time	17 FEB 2022 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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 ☐

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2022 00:01
Patient Cloud Close Date & Time	03 MAR 2022 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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 ☐

FDA-CBER-2022-1614-2918475

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01
Patient Cloud Close Date & Time	10 MAR 2022 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2022 00:01
Patient Cloud Close Date & Time	17 MAR 2022 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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 ☐

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

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 ☐

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

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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 ☐

FDA-CBER-2022-1614-2918483

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

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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 ☐

FDA-CBER-2022-1614-2918485

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2022 00:01
Patient Cloud Close Date & Time	14 APR 2022 23:59

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 ☐

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2022 00:01
Patient Cloud Close Date & Time	28 APR 2022 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2022 00:01
Patient Cloud Close Date & Time	05 MAY 2022 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2022 00:01
Patient Cloud Close Date & Time	12 MAY 2022 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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 ☐

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2022 00:01
Patient Cloud Close Date & Time	19 MAY 2022 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2022 00:01
Patient Cloud Close Date & Time	26 MAY 2022 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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 ☐

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2022 00:01
Patient Cloud Close Date & Time	02 JUN 2022 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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 ☐

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 00:01
Patient Cloud Close Date & Time	09 JUN 2022 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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 ☐

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 00:01
Patient Cloud Close Date & Time	16 JUN 2022 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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 ☐

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 00:01
Patient Cloud Close Date & Time	30 JUN 2022 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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 ☐

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

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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 ☐

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2022 00:01
Patient Cloud Close Date & Time	14 JUL 2022 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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 ☐

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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 ☐

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2022 00:01
Patient Cloud Close Date & Time	28 JUL 2022 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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 ☐

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2022 00:01
Patient Cloud Close Date & Time	04 AUG 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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2022 00:01
Patient Cloud Close Date & Time	11 AUG 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 ☐

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2022 00:01
Patient Cloud Close Date & Time	18 AUG 2022 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2022 00:01
Patient Cloud Close Date & Time	25 AUG 2022 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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 ☐

FDA-CBER-2022-1614-2918525

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

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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 ☐

FDA-CBER-2022-1614-2918527

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2022 00:01
Patient Cloud Close Date & Time	08 SEP 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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2022 00:01
Patient Cloud Close Date & Time	15 SEP 2022 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2022 00:01
Patient Cloud Close Date & Time	22 SEP 2022 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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	25 SEP 2022 00:01
Patient Cloud Close Date & Time	29 SEP 2022 23:59

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	02 OCT 2022 00:01
Patient Cloud Close Date & Time	06 OCT 2022 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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	09 OCT 2022 00:01
Patient Cloud Close Date & Time	13 OCT 2022 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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	16 OCT 2022 00:01
Patient Cloud Close Date & Time	20 OCT 2022 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2022 00:01
Patient Cloud Close Date & Time	27 OCT 2022 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2022 00:01
Patient Cloud Close Date & Time	03 NOV 2022 23:59

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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2022 00:01
Patient Cloud Close Date & Time	10 NOV 2022 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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	13 NOV 2022 00:01
Patient Cloud Close Date & Time	17 NOV 2022 23:59

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58

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 ☐

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

US3662116
Folder: Cosmetic Injections and Dermal Fillers
Form: Cosmetic Injection_ Dermal Filler eDiary
Generated On: 10 Jun 2021 09:24:58

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 06:24:33

FDA-CBER-2022-1614-2918551

US3662116
Folder: Safety Call Day 85 (1)
Form: Safety Call
Data signed: (b) (4) **18 Mar 2021 22:08:23**
Generated On: 10 Jun 2021 09:24:58

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	11 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-2022-1614-2918552

US3662116
Folder: Safety Call Day 85 (1)
Form: Continuing
Data signed: (b) (4) **18 Mar 2021 22:08:23**
Generated On: 10 Jun 2021 09:24:58

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

US3662116
Folder: Safety Call Day 119 (1)
Form: Safety Call
Data signed: (b) (4) **18 Mar 2021 22:08:22**
Generated On: 10 Jun 2021 09:24:58

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	14 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-2022-1614-2918554

US3662116
Folder: Safety Call Day 119 (1)
Form: Continuing
Data signed: (b) (4) **18 Mar 2021 22:08:22**
Generated On: 10 Jun 2021 09:24:58

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

FDA-CBER-2022-1614-2918555

US3662116
Folder: Safety Call Day 149 (1)
Form: Safety Call
Data signed: (b) (4) **18 Mar 2021 22:08:22**
Generated On: 10 Jun 2021 09:24:58

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	12 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-2022-1614-2918556

US3662116
Folder: Safety Call Day 149 (1)
Form: Continuing
Data signed: (b) (4) **18 Mar 2021 22:08:22**
Generated On: 10 Jun 2021 09:24:58

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

FDA-CBER-2022-1614-2918557

US3662116
Folder: Safety Call Day 179 (1)
Form: Safety Call
Data signed: (b) (4) **18 Mar 2021 22:08:22**
Generated On: 10 Jun 2021 09:24:58

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	15 MAR 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-2022-1614-2918558

US3662116
Folder: Safety Call Day 179 (1)
Form: Continuing
Data signed: (b) (4) **18 Mar 2021 22:08:22**
Generated On: 10 Jun 2021 09:24:58

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

FDA-CBER-2022-1614-2918559

US3662116
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Data signed: (b) (4) **28 Apr 2021 13:41:38**
Generated On: 10 Jun 2021 09:24:58

Was this visit performed?	Yes ☑ No ☐
Visit date (dd MMM yyyy)	20 APR 2021
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ☑
Folder OID	VISIT4

FDA-CBER-2022-1614-2918560

US3662116
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Data signed: (b) (4) **28 Apr 2021 13:41:38**
Generated On: 10 Jun 2021 09:24:58

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	20 APR 2021
Time of assessment *(00:00-23:59)*	10:45 (24 HR)
Vital Signs Date and Time (derived)	20 APR 2021 10:45
Temperature *(xxx.x)*	97.9 F
Route of measurement	Oral ☐ Axillary ☐ Other ■
If Other, specify	INFRARED THERMOMETER
Pulse *(xxx)*	87 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	85 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3662116
Folder: Visit 4 Day 209 (1)
Form: Physical Examination
Data signed: (b) (4) **28 Apr 2021 13:41:38**
Generated On: 10 Jun 2021 09:24:58

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.

US3662116
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **28 Apr 2021 13:41:38**
Generated On: 10 Jun 2021 09:24:58

Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	20 APR 2021
Collection time *(00:00-23:59)*	10:51 (24 HR)
Collection date and time (derived)	20 APR 2021 10:51

US3662116
Folder: Visit 4 Day 209 (1)
Form: Continuing
Data signed: (b) (4) **28 Apr 2021 13:41:38**
Generated On: 10 Jun 2021 09:24:58

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

FDA-CBER-2022-1614-2918564

US3662116
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:58

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-2022-1614-2918565

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

US3662116
Folder: Covid-19 Assessment (1)
Form: COVID-19 Contact
Generated On: 10 Jun 2021 09:24:58

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-2022-1614-2918567

US3662116
Folder: Covid-19 Assessment (1)
Form: Generate Next COVID-19 Assessment
Generated On: 10 Jun 2021 09:24:58

Generate Next COVID-19 Assessment	Yes ☐ No ☐

FDA-CBER-2022-1614-2918568

US3662116
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Data signed: (b) (4) **18 Mar 2021 22:08:22**
Generated On: 10 Jun 2021 09:24:58

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	19 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	UNBLND_DECIDE

US3662116
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Data signed: (b) (4) **18 Mar 2021 22:08:22**
Generated On: 10 Jun 2021 09:24:58

Date of updated informed consent *(dd MMM yyyy)*	19 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)*	19 JAN 2021
Participant randomization assignment	mRNA-1273 ■ Placebo ☐
Actual Dose 1	mRNA-1273 ■ Placebo ☐ Not Administered ☐
Actual Dose 2	mRNA-1273 ■ Placebo ☐ Not Administered ☐
Will participant receive mRNA-1273?	Yes ☐ No ■
Placebo Only Flag	
Continuing with mRNA-1273	

US3662116
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **18 Mar 2021 22:08:22**
Generated On: 10 Jun 2021 09:24:58

Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	19 JAN 2021
Collection time *(00:00-23:59)*	09:15 (24 HR)
Collection date and time (derived)	19 JAN 2021 09:15

FDA-CBER-2022-1614-2918571

US3662116
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Data signed: (b) (4) **18 Mar 2021 22:08:22**
Generated On: 10 Jun 2021 09:24:58

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	19 JAN 2021
Collection time *(00:00 - 23:59)*	09:10
Collection Date and Time (derived)	19 JAN 2021 09:10

US3662116
Folder: Adverse Events
Form: Adverse Events Summary
Data signed: (b) (4) **18 Mar 2021 22:08:20**
Generated On: 10 Jun 2021 09:24:58

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

If Yes, enter details on the Adverse Events form.

US3662116
Folder: Adverse Events
Form: Adverse Events (1)
Data signed: (b) (4) **08 Apr 2021 21:54:54**
Generated On: 10 Jun 2021 09:24:58

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

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

US3662116
Folder: Adverse Events
Form: Adverse Events (2)
Data signed: (b) (4) **08 Apr 2021 21:54:54**
Generated On: 10 Jun 2021 09:24:58

AEID	USA-US088-2021-MRNA-1273-P30 1000009
Adverse event	SMALL BOWEL OBSTRUCTION
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)*	10 FEB 2021
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ■
If not Ongoing, end date *(dd MMM yyyy)*	16 FEB 2021
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ■ Grade 4 ☐
Is the adverse event serious?	Yes ■ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date *(dd MMM yyyy)*	11 FEB 2021
Hospital Discharge Date *(dd MMM yyyy)*	16 FEB 2021
Admitted to ICU?	Yes ☐ No ■ Unknown ☐

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ■ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ■ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ■
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	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

PATIENT PRESENTS COMPLAINING OF EPIGASTRIC ABDOMINAL PAIN THAT STARTED LAST EVENING. SHE REPORTS THAT THIS CONTINUED TO GET WORSE, WHICH PROMPTED HER TO COME TO THE ED FOR EVALUATION. SHE ALSO REPORTS SOME NAUSEA WITH 3 EPISODES OF EMESIS. SHE REPORTS THAT HER LAST BOWEL MOVEMENT WAS THIS MORNING AND IT WAS SOFT. SHE DENIES ANY FEVERS, NO CHEST PAIN, NO TROUBLE BREATHING. PATIENT HAS HAD MULTIPLE PREVIOUS ABDOMINAL SURGERIES. SHE IS AFEBRILE AND HEMODYNAMICALLY STABLE. EKG SHOWS STABLE FINDINGS FROM PREVIOUSLY WITHOUT ST ELEVATIONS OR DEPRESSIONS. LABS ARE OVERALL UNREMARKABLE. HIGH SENSITIVITY TROPONIN <3, STABLE ON REPEAT. URINE IS PENDING. CHEST X-RAY IS NEGATIVE. ABDOMINAL X-RAY SHOWS AN INDETERMINATE BOWEL GAS PATTERN. PATIENT HAS A HISTORY OF ABDOMINAL AORTIC DISSECTION, SO CT

ANGIO WAS OBTAINED TO FURTHER ASSESS FOR POSSIBLE CAUSES OF HER PAIN. THIS SHOWED STABLE ABDOMINAL AORTIC DISSECTION IN ADDITION TO SMALL BOWEL OBSTRUCTION WITH TO TRANSITION POINTS AT THE WIDEMOUTH HERNIA.

ACS WAS CONSULTED AND CAME TO SEE THE PATIENT. AND PLACED AN NG TUBE AND WOULD LIKE TO ADMIT THE PATIENT OTHER SERVICE FOR FURTHER MANAGEMENT.

AT THIS TIME THE PATIENT HAS BEEN ADMITTED TO ACS FOR FURTHER EVALUATION AND MANAGEMENT OF SMALL BOWEL OBSTRUCTION.

02.17.2021 UPDATE ABDOMINAL PAIN CONCERN FOR SBO, IMAGING WITH CONCERN AT SITE OF RUQ INCISIONAL HERNIA. NG PLACED AND GASTROGRAFIN TRIAL INITIATED WITH PROGRESSION TO COLON. NG TUBE REMOVED AFTER PATIENT PASSED GRAVITY TRIAL ON 2/12. SHE WAS STARTED ON

	CLEARS AND ADVANCED AS TOLERATED. TOLERATING REGULAR DIET WITH BOWEL FUNCTION AT TIME OF DISCHARGE. STARTED ON BOWEL REGIMEN AT DISCHARGE GIVEN DAILY USE OF TYLENOL-3 PRIOR TO ADMISSION. HYPOKALEMIA REPLETED AND RESOLVED.
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

US3662116
Folder: Adverse Events
Form: Adverse Events (3)
Data signed: (b) (4) **08 Apr 2021 21:54:54**
Generated On: 10 Jun 2021 09:24:58

AEID	
Adverse event	SORE THROAT DUE TO NG TUBE PLACEMENT
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 FEB 2021
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ■
If not Ongoing, end date *(dd MMM yyyy)*	16 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 ☐

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)	

US3662116
Folder: Adverse Events
Form: Adverse Events (4)
Data signed: (b) (4) **08 Apr 2021 21:54:54**
Generated On: 10 Jun 2021 09:24:58

AEID	
Adverse event	WORSENING HTN
Was this a medically-attended AE?	Yes ■ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ■
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ■
Start date *(dd MMM yyyy)*	12 FEB 2021
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ■
If not Ongoing, end date *(dd MMM yyyy)*	15 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 ☐
Number of Days in ICU	

FDA-CBER-2022-1614-2918583

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)	

US3662116
Folder: Adverse Events
Form: Adverse Events (5)
Data signed: (b) (4) **08 Apr 2021 21:54:54**
Generated On: 10 Jun 2021 09:24:58

AEID	
Adverse event	SINUSITIS
Was this a medically-attended AE?	Yes ■ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ■
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ■
Start date *(dd MMM yyyy)*	14 FEB 2021
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ■
If not Ongoing, end date *(dd MMM yyyy)*	16 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 ☐
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)	

US3662116
Folder: Adverse Events
Form: Adverse Events (6)
Data signed: (b) (4) **08 Apr 2021 21:54:54**
Generated On: 10 Jun 2021 09:24:58

AEID	
Adverse event	INSOMNIA
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)*	14 FEB 2021
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ■
If not Ongoing, end date *(dd MMM yyyy)*	15 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 ☐
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)	

US3662116
Folder: Adverse Events
Form: Adverse Events (7)
Data signed: (b) (4) **08 Apr 2021 21:54:54**
Generated On: 10 Jun 2021 09:24:58

AEID	
Adverse event	NAUSEA, INTERMITTENT POST SMALL BOWEL OBSTRUCTION
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)*	16 FEB 2021
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ■ No ☐
If not Ongoing, end date *(dd MMM yyyy)*	
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)	

US3662116
Folder: Adverse Events
Form: Adverse Events (8)
Data signed: (b) (4) **08 Apr 2021 21:54:54**
Generated On: 10 Jun 2021 09:24:58

AEID	
Adverse event	HYPOKALEMIA
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)*	13 FEB 2021
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ■
If not Ongoing, end date *(dd MMM yyyy)*	13 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 ☐
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)	

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Data signed: (b) (4) **18 Mar 2021 22:08:22**
Generated On: 10 Jun 2021 09:24:58

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

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

FDA-CBER-2022-1614-2918593

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Data signed: (b) (4) **08 Apr 2021 21:54:54**
Generated On: 10 Jun 2021 09:24:58

Name of Medication	AMLODIPINE BESYLATE
Prophylaxis	Yes ☐ No ■
Indication	HYPERTENSION
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 ☐

FDA-CBER-2022-1614-2918594

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	01 JUL 2001
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 ■

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Data signed: (b) (4) **08 Apr 2021 21:54:54**
Generated On: 10 Jun 2021 09:24:58

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

FDA-CBER-2022-1614-2918596

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	01 JUL 2001
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 ■

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Data signed: (b) (4) **08 Apr 2021 21:54:54**
Generated On: 10 Jun 2021 09:24:58

Name of Medication	TYLENOL
Prophylaxis	Yes ☐ No ■
Indication	ARM PAIN/FEVER
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 ☐

FDA-CBER-2022-1614-2918598

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

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Data signed: (b) (4) **08 Apr 2021 21:54:54**
Generated On: 10 Jun 2021 09:24:58

Name of Medication	METFORMIN
Prophylaxis	Yes ☐ No ■
Indication	PRE-DIABETIC
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)*	16 NOV 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 ■

Name of Medication	ACETAMINOPHEN ; COMB; CODEINE PHOSPHATE
Prophylaxis	Yes ☐ No ■
Indication	GENERALIZED PAIN
Dose per administration	300/30
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ■
If frequency is Other, specify	EVERY FOUR TO 6 HOURS
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐

	Intraocular ☐
	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	1 NOV 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 ☐

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Data signed: (b) (4) **08 Apr 2021 21:54:54**
Generated On: 10 Jun 2021 09:24:58

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

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	7 JUL 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	4 MAR 2021
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

Name of Medication	ESOMEPRAZOLE; NEXIUM
Prophylaxis	Yes ☐ No ■
Indication	GERD
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)*	7 JUL 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 ■

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Data signed: (b) (4) **08 Apr 2021 21:54:54**
Generated On: 10 Jun 2021 09:24:58

Name of Medication	TYLENOL
Prophylaxis	Yes ☐ No ■
Indication	ARM PAIN/FEVER
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)*	17 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	17 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 ☐

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Data signed: (b) (4) **08 Apr 2021 21:54:54**
Generated On: 10 Jun 2021 09:24:58

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

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ■
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	11 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	11 FEB 2021
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Data signed: (b) (4) **08 Apr 2021 21:54:54**
Generated On: 10 Jun 2021 09:24:58

Name of Medication	ZOFRAN
Prophylaxis	Yes ☐ No ■
Indication	SMALL BOWEL OBSTRUCTION
Dose per administration	4
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ■ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

FDA-CBER-2022-1614-2918612

	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 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	16 FEB 2021
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

Name of Medication	PANTOPRAZOLE ; PROTONIX
Prophylaxis	Yes ☐ No ■
Indication	SMALL BOWEL OBSTRUCTION
Dose per administration	40
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ■
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	11 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	14 FEB 2021
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

Name of Medication	OMNIPAQUE ; SEE IOHEXOL
Prophylaxis	Yes ☐
	No ■
Indication	SMALL BOWEL OBSTRUCTION
Dose per administration	150
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 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	11 FEB 2021
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

Name of Medication	MORPHINE
Prophylaxis	Yes ☐ No ■
Indication	SMALL BOWEL OBSTRUCTION
Dose per administration	4
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ■ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ■
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	11 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	11 FEB 2021
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Data signed: (b) (4) **08 Apr 2021 21:54:54**
Generated On: 10 Jun 2021 09:24:58

Name of Medication	METHOCARBAMOL
Prophylaxis	Yes ☐ No ■
Indication	SMALL BOWEL OBSTRUCTION
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	EVERY 8 HOURS
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ■
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	11 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	14 FEB 2021
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Data signed: (b) (4) **08 Apr 2021 21:54:54**
Generated On: 10 Jun 2021 09:24:58

Name of Medication	LIDOCAINE HCL 2% VISCOUS SOLUTION
Prophylaxis	Yes ☐ No ■
Indication	SORE THROAT DUE TO NG TUBE PLACEMENT
Dose per administration	15
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 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	12 FEB 2021
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Data signed: (b) (4) **08 Apr 2021 21:54:54**
Generated On: 10 Jun 2021 09:24:58

Name of Medication	LACTATED RINGERS
Prophylaxis	Yes ☐ No ■
Indication	SMALL BOWEL OBSTRUCTION
Dose per administration	125
Dose unit	mg ☐ ug ☐ mL ■ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ■
If frequency is Other, specify	125 ML / HOUR
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 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	13 FEB 2021
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

Name of Medication	HYDROMORPHONE HCL
Prophylaxis	Yes ☐ No ■
Indication	SMALL BOWEL OBSTRUCTION
Dose per administration	0.5
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	EVERY 4-6 HOURS
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ■
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	11 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	15 FEB 2021
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Data signed: (b) (4) **08 Apr 2021 21:54:54**
Generated On: 10 Jun 2021 09:24:58

Name of Medication	HEPARIN
Prophylaxis	Yes ☐ No ■
Indication	SMALL BOWEL OBSTRUCTION
Dose per administration	5000
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ■
If dose unit is Other, specify	UNITS
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 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	16 FEB 2021
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	3
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Data signed: (b) (4) **08 Apr 2021 21:54:54**
Generated On: 10 Jun 2021 09:24:58

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

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ■
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	11 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	11 FEB 2021
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

Name of Medication	DIATRIZOATE MEGLUMINE ; COMB; DIATRIZOATE SODIUM
Prophylaxis	Yes ☐ No ■
Indication	SMALL BOWEL OBSTRUCTION
Dose per administration	120
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 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	12 FEB 2021
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Data signed: (b) (4) **08 Apr 2021 21:54:54**
Generated On: 10 Jun 2021 09:24:58

Name of Medication	PHENOL 1.4%
Prophylaxis	Yes ☐ No ■
Indication	SORE THROAT DUE TO NG TUBE PLACEMENT
Dose per administration	5
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ■
If dose unit is Other, specify	SPRAYS
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ■ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ■ Subcutaneous ☐ Transdermal ☐

	Intraocular ☐
	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	12 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	16 FEB 2021
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Data signed: (b) (4) **08 Apr 2021 21:54:54**
Generated On: 10 Jun 2021 09:24:58

Name of Medication	INFLUENZA QUADRIVALENT
Prophylaxis	Yes ■ No ☐
Indication	SEASONAL FLU VACCINE
Dose per administration	0.5
Dose unit	mg ☐ ug ☐ mL ■ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ■ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

FDA-CBER-2022-1614-2918636

	Intramuscular ■
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	12 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	12 FEB 2021
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Data signed: (b) (4) **08 Apr 2021 21:54:54**
Generated On: 10 Jun 2021 09:24:58

Name of Medication	HYDROMORPHONE HCL
Prophylaxis	Yes ☐ No ■
Indication	SMALL BOWEL OBSTRUCTION
Dose per administration	0.3
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ■
If frequency is Other, specify	EVERY 4 TO 6 HOURS AS NEEDED
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐

	Intraocular ☐
	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ■
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	12 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	13 FEB 2021
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Data signed: (b) (4) **08 Apr 2021 21:54:54**
Generated On: 10 Jun 2021 09:24:58

Name of Medication	HYDRALAZINE HCL
Prophylaxis	Yes ☐ No ■
Indication	WORSENING HTN
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 ☐

FDA-CBER-2022-1614-2918640

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ■
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	12 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	15 FEB 2021
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Data signed: (b) (4) **08 Apr 2021 21:54:54**
Generated On: 10 Jun 2021 09:24:58

Name of Medication	HYDRALAZINE HCL
Prophylaxis	Yes ☐ No ■
Indication	SMALL BOWEL OBSTRUCTION
Dose per administration	20
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ■
If dose unit is Other, specify	MG/ML
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ■
If frequency is Other, specify	EVERY 4 TO SIX HOURS AS NEEDED
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐

	Intraocular ☐
	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ■
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	12 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	15 FEB 2021
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Data signed: (b) (4) **08 Apr 2021 21:54:54**
Generated On: 10 Jun 2021 09:24:58

Name of Medication	TYLENOL
Prophylaxis	Yes ☐ No ■
Indication	SMALL BOWEL OBSTRUCTION
Dose per administration	975
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ■
If frequency is Other, specify	EVERY 8 HOURS
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

FDA-CBER-2022-1614-2918644

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	13 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	15 FEB 2021
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Data signed: (b) (4) **08 Apr 2021 21:54:54**
Generated On: 10 Jun 2021 09:24:58

Name of Medication	POTASSIUM CHLORIDE
Prophylaxis	Yes ☐ No ■
Indication	HYPOKALEMIA
Dose per administration	10
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ■
If dose unit is Other, specify	MEQ
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ■
If frequency is Other, specify	EVERY HOUR
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ■
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	13 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	13 FEB 2021
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Data signed: (b) (4) **08 Apr 2021 21:54:54**
Generated On: 10 Jun 2021 09:24:58

Name of Medication	MIRALAX
Prophylaxis	Yes ☐ No ■
Indication	SMALL BOWEL OBSTRUCTION/ PREVENTION OF REOCCURRENCE
Dose per administration	17
Dose unit	mg ☐ ug ☐ mL ☐ g ■ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐

FDA-CBER-2022-1614-2918648

	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)*	14 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Data signed: (b) (4) **08 Apr 2021 21:54:54**
Generated On: 10 Jun 2021 09:24:58

Name of Medication	MELATONIN
Prophylaxis	Yes ☐ No ■
Indication	INSOMNIA
Dose per administration	3
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-2022-1614-2918650

	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)*	14 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	15 FEB 2021
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (30)
Data signed: (b) (4) **08 Apr 2021 21:54:54**
Generated On: 10 Jun 2021 09:24:58

Name of Medication	AFRIN NASAL SOLUTION 0.05%
Prophylaxis	Yes ☐ No ■
Indication	SINUSITIS
Dose per administration	2
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ■
If dose unit is Other, specify	SPRAYS
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)*	14 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	16 FEB 2021
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 ■

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (31)
Data signed: (b) (4) **08 Apr 2021 21:54:54**
Generated On: 10 Jun 2021 09:24:58

Name of Medication	SENNA-DOCUSATE
Prophylaxis	Yes ☐ No ■
Indication	SMALL BOWEL OBSTRUCTION/ PREVENTION OF REOCCURRENCE
Dose per administration	8.6-50
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐

	Intraocular ☐
	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	15 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (32)
Data signed: (b) (4) **08 Apr 2021 21:54:54**
Generated On: 10 Jun 2021 09:24:58

Name of Medication	GABAPENTIN ; NEURONTIN
Prophylaxis	Yes ☐ No ■
Indication	SMALL BOWEL OBSTRUCTION/ PREVENTION OF REOCCURRENCE
Dose per administration	100
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ■ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐

	Intraocular ☐
	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	15 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	3
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (33)
Data signed: (b) (4) **08 Apr 2021 21:54:54**
Generated On: 10 Jun 2021 09:24:58

Name of Medication	ZOFRAN
Prophylaxis	Yes ☐ No ■
Indication	NAUSEA
Dose per administration	4
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ■ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	16 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (34)
Data signed: (b) (4) **08 Apr 2021 21:54:54**
Generated On: 10 Jun 2021 09:24:58

Name of Medication	PANTOPRAZOLE ; PROTONIX
Prophylaxis	Yes ☐ No ■
Indication	SMALL BOWEL OBSTRUCTION
Dose per administration	40
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ■ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

FDA-CBER-2022-1614-2918660

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	16 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	16 FEB 2021
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (35)
Data signed: (b) (4) **08 Apr 2021 21:54:54**
Generated On: 10 Jun 2021 09:24:58

Name of Medication	HYDROCHLOROTHIAZIDE
Prophylaxis	Yes ☐ No ■
Indication	HYPERTENSION
Dose per administration	12.5
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)*	15 MAR 2021
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (36)
Data signed: (b) (4) **08 Apr 2021 21:54:54**
Generated On: 10 Jun 2021 09:24:58

Name of Medication	GASTROGRAFIN (DIATRIZOATE MEGLUMINE AND SODIUM)
Prophylaxis	Yes ☐ No ■
Indication	NG TUBE PLACEMENT, PROCEDURE
Dose per administration	120
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	VIA NG TUBE
Start date *(dd MMM yyyy)*	11 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	11 FEB 2021
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (37)
Data signed: (b) (4) **08 Apr 2021 21:54:54**
Generated On: 10 Jun 2021 09:24:58

Name of Medication	TRAZODONE HCL
Prophylaxis	Yes ☐ No ■
Indication	ANXIETY/INSOMNIA
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-2022-1614-2918666

	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)*	8 SEP 2017
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

US3662116
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Data signed: (b) (4) **18 Mar 2021 22:08:22**
Generated On: 10 Jun 2021 09:24:58

Were any concomitant procedures performed?	Yes ■ No ☐

If yes, please complete Concomitant Procedures form.

US3662116
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures
Data signed: (b) (4) **08 Apr 2021 21:54:54**
Generated On: 10 Jun 2021 09:24:58

Procedure/Surgery date *(dd MMM yyyy)*	Procedure/Surgery	Indication	If indication is Other, specify
12 FEB 2021	PICC PLACEMENT	Adverse Event	
11 FEB 2021	NG TUBE PLACEMENT	Adverse Event	
11 FEB 2021	BEDSIDE FOCUSED FAST ULTRASOUND	Diagnostic	
11 FEB 2021	XRAY PORTABLE CHEST	Diagnostic	
11 FEB 2021	XRAY PORTABLE ABDOMEN AP VIEW	Diagnostic	
11 FEB 2021	CT ANGIO CHEST WITH AND/OR WITHOUT	Diagnostic	
11 FEB 2021	CT ANGIO ABDOMEN PELVIS WITH AND/OR WITHOUT IV CONTRAST	Diagnostic	
11 FEB 2021	XR PORTABLE FEEDING TUBE CHECK	Diagnostic	
12 FEB 2021	XRAY PORTABLE ABDOMINAL AP VIEW	Adverse Event	
11 FEB 2021	XRAY PORTABLE ABDOMEN AP VIEW	Diagnostic	
12 FEB 2021	ECG 12 LEAD	Adverse Event	

FDA-CBER-2022-1614-2918669

US3662116
Folder: End of Study (1)
Form: Dosing Discontinuation
Generated On: 10 Jun 2021 09:24:58

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	

US3662116
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 10 Jun 2021 09:24:58

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 ☐

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Data signed: (b) (4) **08 Apr 2021 21:54:54**
Generated On: 10 Jun 2021 09:24:58

SAEID	USA-US088-2021-MRNA-1273-P301000009
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	CARL
Investigator's Last Name	FICHTENBAUM
Site Address: Street	231 ALBERT SABIN WAY
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45267
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form (1)
Data signed: (b) (4) **08 Apr 2021 21:54:54**
Generated On: 10 Jun 2021 09:24:58

SAEID	USA-US088-2021-MRNA-1273-P301000009
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	CARL
Investigator's Last Name	FICHTENBAUM
Site Address: Street	231 ALBERT SABIN WAY
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45267
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	16/FEB/2021 09:47
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

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form (2)
Data signed: (b) (4) **08 Apr 2021 21:54:54**
Generated On: 10 Jun 2021 09:24:58

SAEID	USA-US088-2021-MRNA-1273-P301000009
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	CARL
Investigator's Last Name	FICHTENBAUM
Site Address: Street	231 ALBERT SABIN WAY
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45267
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	18/FEB/2021 14:17
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form (3)
Data signed: (b) (4) **08 Apr 2021 21:54:54**
Generated On: 10 Jun 2021 09:24:58

SAEID	USA-US088-2021-MRNA-1273-P301000009
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	CARL
Investigator's Last Name	FICHTENBAUM
Site Address: Street	231 ALBERT SABIN WAY
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45267
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	23/FEB/2021 15:21
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

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form (4)
Data signed: (b) (4) **08 Apr 2021 21:54:54**
Generated On: 10 Jun 2021 09:24:58

SAEID	USA-US088-2021-MRNA-1273-P301000009
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	CARL
Investigator's Last Name	FICHTENBAUM
Site Address: Street	231 ALBERT SABIN WAY
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45267
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	25/MAR/2021 11:29
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

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form (5)
Data signed: (b) (4) **08 Apr 2021 21:54:54**
Generated On: 10 Jun 2021 09:24:58

SAEID	USA-US088-2021-MRNA-1273-P301000009
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	CARL
Investigator's Last Name	FICHTENBAUM
Site Address: Street	231 ALBERT SABIN WAY
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45267
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	07/APR/2021 08:57
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3662116 (Prod: Cincinnati CRS)

US3662116
Form: Participant Creation
Generated On: 10 Jun 2021 09:24:58
Participant ID

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:56:20
User entered 'US3662116'	RWS_ENDPOINT ENDPOINT (b) (4)	18 Sep 2020 12:39:28

US3662116
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 09:24:58
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:21:11
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:01:43

US3662116
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 09:24:58
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 13:21:11
User entered '18 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	18 Sep 2020 12:39:29

FDA-CBER-2022-1614-2918681

US3662116
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 09:24:58
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:21:11
User entered 'Clinic (Clinic)'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:01:43

US3662116
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 09:24:58
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered 'SCRN'	System	22 Sep 2020 14:01:43

US3662116
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:24:58
Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 13:21:50
User entered (b) (6) 1965'	RWS_ENDPOINT ENDPOINT (b) (4)	18 Sep 2020 12:39:30

FDA-CBER-2022-1614-2918684

US3662116
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:24:58
Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:21:50
User entered '54'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:02:22

US3662116
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:24:58
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered 'YEARS'	System	22 Sep 2020 14:02:22

US3662116
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:24:58
Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered '54'	System	18 Sep 2020 13:02:43

FDA-CBER-2022-1614-2918687

US3662116
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:24:58
Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:21:50
User entered 'Female (F)'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:02:22

US3662116
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:24:58
Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:21:50
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Brenda Miller (b) (4)	22 Sep 2020 14:02:22

US3662116
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:24:58
White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:21:50
User entered '0'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:02:22

US3662116
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:24:58
Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:21:50
User entered '1'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:02:22

US3662116
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:24:58
Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:21:50
User entered '0'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:02:22

US3662116
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:24:58
American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:21:50
User entered '0'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:02:22

US3662116
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:24:58
Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:21:50
User entered '0'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:02:22

US3662116
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:24:58
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:21:50
User entered '0'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:02:22

US3662116
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:24:58
If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:21:50
User entered empty.	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:02:22

US3662116
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:24:58
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:21:50
User entered '0'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:02:22

US3662116
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:24:58
Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:21:50
User entered '0'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:02:22

US3662116
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:24:58
Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:22:01
User entered '18 Sep 2020'	michelle saemann (b) (4) (b) (4)	18 Sep 2020 13:02:43

US3662116
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:24:58
Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered 'Sep 2020'	System	18 Sep 2020 13:02:43

US3662116
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:24:58
Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered '2020'	System	18 Sep 2020 13:02:43

US3662116
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:24:58
Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:22:01
User entered 'Amendment 3 (3)'	michelle saemann (b) (4) (b) (4)	18 Sep 2020 13:02:43

US3662116
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:24:58
Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:22:01
User entered 'Yes (Y)'	michelle saemann (b) (4) (b) (4)	18 Sep 2020 13:02:43

US3662116
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:24:58
If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:22:01
User entered empty.	michelle saemann (b) (4) (b) (4)	18 Sep 2020 13:02:43

US3662116
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:24:58
If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:22:01
User entered empty.	michelle saemann (b) (4) (b) (4)	18 Sep 2020 13:02:43

US3662116
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:24:58
Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:22:01
User entered 'No (N)'	michelle saemann (b) (4) (b) (4)	18 Sep 2020 13:02:43

US3662116
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:24:58
If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:22:01
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	18 Sep 2020 12:39:29

US3662116
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:24:58
Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered '1'	System	18 Sep 2020 13:02:50

US3662116
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Generated On: 10 Jun 2021 09:24:58
Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 13:22:05
User entered 'Yes (Y)'	michelle saemann (b) (4) (b) (4)	18 Sep 2020 13:02:50

US3662116
Folder: Screening
Form: Medical History Summary
Generated On: 10 Jun 2021 09:24:58
Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:22:10
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:02:45

US3662116
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:24:58
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Bone disorders NEC, PT: Exostosis, LLT: Exostosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:09:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:09:33
Data point term sent to Coder	System	18 Mar 2021 22:08:49
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:06:15
User closed query 'Per source, bone spur of left knee. Please update to include location if appropriate' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 16:06:12
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Bone disorders NEC, PT: Exostosis, LLT: Exostosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 07:33:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 07:33:54
Query 'Per source, bone spur of left knee. Please update to include location if appropriate' answered with 'Corrected data' (Site from CRA).	Brenda Miller (b) (4) (b) (4)	16 Nov 2020 18:46:26
Data point term sent to Coder	System	16 Nov 2020 18:46:25
Coding entries removed.	Brenda Miller (b) (4) (b) (4)	16 Nov 2020 18:46:07
User entered 'EXOSTOSIS - BONE SPUR LEFT KNEE' reason for change: Data Entry Error	Brenda Miller (b) (4) (b) (4)	16 Nov 2020 18:46:07
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 20:01:09
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:00:52
User opened query 'Per source, bone spur of left knee. Please update to include location if appropriate' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:58:54

US3662116
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:24:58
Condition

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Bone disorders NEC, PT: Exostosis, LLT: Exostosis of unspecified site - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 14:04:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 14:04:35
Data point term sent to Coder	System	22 Sep 2020 14:03:55
User entered 'EXOSTOSIS OF UNSPECIFIED SITE'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:03:18

US3662116
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:24:58
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:00:52
User entered '07 Jul 2020'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:03:18

US3662116
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:24:58
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:00:52
User entered '0'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:03:18

US3662116
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:24:58
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:00:52
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:03:18

US3662116
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:24:58
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:00:52
User entered empty.	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:03:18

US3662116
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:24:58
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:00:52
User entered '0'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:03:18

US3662116
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:24:58
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered 'Jul 2020'	System	22 Sep 2020 14:03:18

US3662116
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:24:58
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered '2020'	System	22 Sep 2020 14:03:18

FDA-CBER-2022-1614-2918719

US3662116
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:24:58
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered empty.	System	22 Sep 2020 14:03:18

US3662116
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:24:58
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered empty.	System	22 Sep 2020 14:03:18

US3662116
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:24:58
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Knee pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:24:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:24:51
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Knee pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:09:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:09:43
Data point term sent to Coder	System	18 Mar 2021 22:08:49
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:00:52
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Knee pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 14:04:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 14:04:34
Data point term sent to Coder	System	22 Sep 2020 14:03:54
User entered 'LEFT KNEE PAIN'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:03:39

US3662116
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:24:58
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:00:52
User entered '01 Jul 2020'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:03:39

US3662116
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:24:58
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:00:52
User entered '0'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:03:39

US3662116
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:24:58
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:00:52
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:03:39

US3662116
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:24:58
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:00:52
User entered empty.	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:03:39

US3662116
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:24:58
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:00:52
User entered '0'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:03:39

US3662116
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:24:58
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered 'Jul 2020'	System	22 Sep 2020 14:03:39

US3662116
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:24:58
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered '2020'	System	22 Sep 2020 14:03:39

FDA-CBER-2022-1614-2918729

US3662116
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:24:58
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered empty.	System	22 Sep 2020 14:03:39

US3662116
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:24:58
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered empty.	System	22 Sep 2020 14:03:39

US3662116
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:24:58
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Morbid obesity - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:10:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:10:12
Data point term sent to Coder	System	18 Mar 2021 22:08:49
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:37:42
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Morbid obesity - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 14:05:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 14:05:42
Data point term sent to Coder	System	22 Sep 2020 14:04:56
User entered 'MORBID OBESITY'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:04:02

US3662116
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:24:58
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:37:44
User entered '08 Jul 2014'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:04:02

US3662116
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:24:58
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:37:45
User entered '0'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:04:02

US3662116
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:24:58
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:37:50
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:04:02

US3662116
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:24:58
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:37:51
User entered empty.	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:04:02

US3662116
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:24:58
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:37:53
User entered '0'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:04:02

US3662116
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:24:58
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered 'Jul 2014'	System	22 Sep 2020 14:04:02

US3662116
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:24:58
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered '2014'	System	22 Sep 2020 14:04:02

FDA-CBER-2022-1614-2918739

US3662116
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:24:58
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered empty.	System	22 Sep 2020 14:04:02

US3662116
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:24:58
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered empty.	System	22 Sep 2020 14:04:02

FDA-CBER-2022-1614-2918741

US3662116
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:24:58
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
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)	18 Mar 2021 22:09:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:09:34
Data point term sent to Coder	System	18 Mar 2021 22:08:51
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:37:57
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)	22 Sep 2020 14:05:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 14:05:42
Data point term sent to Coder	System	22 Sep 2020 14:04:56
User entered 'HYPERTENSION NEC'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:04:21

US3662116
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:24:58
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:37:59
User entered '01 Jul 2001'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:04:21

US3662116
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:24:58
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:38:01
User entered '0'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:04:21

US3662116
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:24:58
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:38:10
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:04:21

US3662116
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:24:58
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:38:08
User entered empty.	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:04:21

US3662116
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:24:58
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:38:06
User entered '0'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:04:21

US3662116
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:24:58
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered 'Jul 2001'	System	22 Sep 2020 14:04:21

US3662116
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:24:58
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered '2001'	System	22 Sep 2020 14:04:21

US3662116
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:24:58
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered empty.	System	22 Sep 2020 14:04:21

US3662116
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:24:58
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered empty.	System	22 Sep 2020 14:04:21

US3662116
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 09:24:58
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Total abdominal hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:10:03
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:10:03
Data point term sent to Coder	System	18 Mar 2021 22:08:52
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:00:52
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Total abdominal hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Oct 2020 15:37:06
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Oct 2020 15:37:06
Data point term sent to Coder	System	26 Oct 2020 13:41:43
User entered 'COMPLETE ABDOMINAL HYSTERECTOMY'	Brenda Miller (b) (4) (b) (4)	26 Oct 2020 13:40:50

US3662116
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 09:24:58
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:00:52
User entered '31 May 2018' reason for change: Data Entry Error	michelle saemann (b) (4)	03 Nov 2020 21:17:20
User entered '01 Jun 2005'	Brenda Miller (b) (4)	26 Oct 2020 13:40:50

US3662116
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 09:24:58
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:00:52
User entered '0'	Brenda Miller (b) (4) (b) (4)	26 Oct 2020 13:40:50

US3662116
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 09:24:58
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:00:52
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	26 Oct 2020 13:40:50

US3662116
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 09:24:58
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:00:52
User entered '31 May 2018' reason for change: Data Entry Error	michelle saemann (b) (4) (b) (4)	03 Nov 2020 21:16:30
User entered '01 Jul 2005'	Brenda Miller (b) (4) (b) (4)	26 Oct 2020 13:40:50

US3662116
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 09:24:58
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:00:52
User entered '0'	Brenda Miller (b) (4) (b) (4)	26 Oct 2020 13:40:50

US3662116
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 09:24:58
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered 'May 2018'	System	03 Nov 2020 21:17:20
User entered 'Jun 2005'	System	26 Oct 2020 13:40:50

US3662116
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 09:24:58
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered '2018'	System	03 Nov 2020 21:17:20
User entered '2005'	System	26 Oct 2020 13:40:50

US3662116
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 09:24:58
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered 'May 2018'	System	03 Nov 2020 21:16:30
User entered 'Jul 2005'	System	26 Oct 2020 13:40:50

US3662116
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 09:24:58
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered '2018'	System	03 Nov 2020 21:16:30
User entered '2005'	System	26 Oct 2020 13:40:50

US3662116
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 09:24:58
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Uterine, pelvic and broad ligament disorders, HLT: Pelvis and broad ligament disorders NEC, PT: Adnexa uteri mass, LLT: Adnexal mass - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:10:12
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:10:12
Data point term sent to Coder	System	18 Mar 2021 22:08:49
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:00:52
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Uterine, pelvic and broad ligament disorders, HLT: Pelvis and broad ligament disorders NEC, PT: Adnexa uteri mass, LLT: Adnexal mass - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Nov 2020 04:51:20
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Nov 2020 04:51:20
Data point term sent to Coder	System	03 Nov 2020 21:17:38
User entered 'adenexal mass'	michelle saemann (b) (4) (b) (4)	03 Nov 2020 21:16:59

US3662116
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 09:24:58
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:00:52
User entered '15 Dec 2017'	michelle saemann (b) (4) (b) (4)	03 Nov 2020 21:16:59

US3662116
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 09:24:58
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:00:52
User entered '0'	michelle saemann (b) (4) (b) (4)	03 Nov 2020 21:16:59

US3662116
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 09:24:58
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:00:52
User entered 'No (N)'	michelle saemann (b) (4) (b) (4)	03 Nov 2020 21:16:59

US3662116
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 09:24:58
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:00:52
User entered '31 May 2018'	michelle saemann (b) (4) (b) (4)	03 Nov 2020 21:16:59

US3662116
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 09:24:58
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:00:52
User entered '0'	michelle saemann (b) (4) (b) (4)	03 Nov 2020 21:16:59

US3662116
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 09:24:58
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered 'Dec 2017'	System	03 Nov 2020 21:16:59

US3662116
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 09:24:58
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered '2017'	System	03 Nov 2020 21:16:59

FDA-CBER-2022-1614-2918769

US3662116
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 09:24:58
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered 'May 2018'	System	03 Nov 2020 21:16:59

FDA-CBER-2022-1614-2918770

US3662116
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 09:24:58
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered '2018'	System	03 Nov 2020 21:16:59

US3662116
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:24:58
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:58:08
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Pain, LLT: General body pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:24:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:24:51
Data point term sent to Coder	System	18 Mar 2021 22:08:52
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Pain, LLT: General body pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Mar 2021 13:32:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Mar 2021 13:32:50
Data point term sent to Coder	System	15 Mar 2021 12:56:45
User entered 'chronic generalized pain'	Angela Snyder (b) (4) (b) (4)	15 Mar 2021 12:55:51

US3662116
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:24:58
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:58:08
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '1 Nov 2019'	Angela Snyder (b) (4) (b) (4)	15 Mar 2021 12:55:51

US3662116
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:24:58
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:58:08
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	15 Mar 2021 12:55:51

US3662116
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:24:58
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:58:08
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	15 Mar 2021 12:55:51

US3662116
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:24:58
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:58:08
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	15 Mar 2021 12:55:51

US3662116
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:24:58
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:58:08
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	15 Mar 2021 12:55:51

US3662116
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:24:58
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered 'Nov 2019'	System	15 Mar 2021 12:55:51

FDA-CBER-2022-1614-2918778

US3662116
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:24:58
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered '2019'	System	15 Mar 2021 12:55:51

FDA-CBER-2022-1614-2918779

US3662116
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:24:58
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered empty.	System	15 Mar 2021 12:55:51

US3662116
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:24:58
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered empty.	System	15 Mar 2021 12:55:51

US3662116
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 09:24:58
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:58:08
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:24:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:24:55
Data point term sent to Coder	System	18 Mar 2021 22:08:50
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Mar 2021 12:56:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Mar 2021 12:56:56
Data point term sent to Coder	System	15 Mar 2021 12:56:43
User entered 'gastro-esophageal reflux disease'	Angela Snyder (b) (4) (b) (4)	15 Mar 2021 12:56:27

US3662116
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 09:24:58
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:58:08
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '22 Mar 2019'	Angela Snyder (b) (4) (b) (4)	15 Mar 2021 12:56:27

US3662116
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 09:24:58
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:58:08
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	15 Mar 2021 12:56:27

US3662116
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 09:24:58
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:58:08
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	15 Mar 2021 12:56:27

US3662116
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 09:24:58
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:58:08
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	15 Mar 2021 12:56:27

US3662116
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 09:24:58
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:58:08
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	15 Mar 2021 12:56:27

US3662116
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 09:24:58
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered 'Mar 2019'	System	15 Mar 2021 12:56:27

US3662116
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 09:24:58
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered '2019'	System	15 Mar 2021 12:56:27

US3662116
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 09:24:58
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered empty.	System	15 Mar 2021 12:56:27

FDA-CBER-2022-1614-2918790

US3662116
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 09:24:58
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered empty.	System	15 Mar 2021 12:56:27

US3662116
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 09:24:58
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	16 Apr 2021 19:05:54
User coded data point as SOC: Vascular disorders, HLGT: Aneurysms and artery dissections, HLT: Aortic aneurysms and dissections, PT: Aortic dissection, LLT: Aortic dissection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Mar 2021 14:39:17
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Mar 2021 14:39:17
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:58:08
Data point term sent to Coder	System	24 Mar 2021 12:57:40
Coding entries removed.	michelle saemann (b) (4) (b) (4)	24 Mar 2021 12:56:51
User entered 'Infra-renal aortic dissection' reason for change: New Information	michelle saemann (b) (4) (b) (4)	24 Mar 2021 12:56:51
User coded data point as SOC: Vascular disorders, HLGT: Aneurysms and artery dissections, HLT: Aortic aneurysms and dissections, PT: Aortic dissection, LLT: Dissecting aortic aneurysm, unspecified site - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Mar 2021 06:32:28
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Mar 2021 06:32:28
Data point term sent to Coder	System	23 Mar 2021 15:51:29
User entered 'dissecting aortic aneur unspecified site'	Angela Snyder (b) (4) (b) (4)	23 Mar 2021 15:51:00

US3662116
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 09:24:58
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	16 Apr 2021 19:05:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:58:08
User entered '1 Apr 2014'	Angela Snyder (b) (4) (b) (4)	23 Mar 2021 15:51:00

US3662116
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 09:24:58
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	16 Apr 2021 19:05:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:58:08
User entered '0'	Angela Snyder (b) (4) (b) (4)	23 Mar 2021 15:51:00

US3662116
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 09:24:58
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	16 Apr 2021 19:05:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:58:08
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	23 Mar 2021 15:51:00

US3662116
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 09:24:58
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	16 Apr 2021 19:05:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:58:08
User entered empty.	Angela Snyder (b) (4) (b) (4)	23 Mar 2021 15:51:00

US3662116
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 09:24:58
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	16 Apr 2021 19:05:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:58:08
User entered '0'	Angela Snyder (b) (4) (b) (4)	23 Mar 2021 15:51:00

US3662116
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 09:24:58
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered 'Apr 2014'	System	23 Mar 2021 15:51:00

FDA-CBER-2022-1614-2918798

US3662116
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 09:24:58
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered '2014'	System	23 Mar 2021 15:51:00

FDA-CBER-2022-1614-2918799

US3662116
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 09:24:58
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered empty.	System	23 Mar 2021 15:51:00

US3662116
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 09:24:58
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered empty.	System	23 Mar 2021 15:51:00

US3662116
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 09:24:58
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	16 Apr 2021 19:05:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:58:08
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Hepatobiliary neoplasms malignant and unspecified, HLT: Gallbladder neoplasms malignant, PT: Gallbladder cancer, LLT: Malignant neoplasm of gallbladder - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Mar 2021 15:55:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Mar 2021 15:55:45
Data point term sent to Coder	System	23 Mar 2021 15:54:34
User entered 'malignant neoplasm of gallbladder'	Angela Snyder (b) (4) (b) (4)	23 Mar 2021 15:53:35

US3662116
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 09:24:58
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:58:08
User entered '10 Apr 2014' reason for change: Data Entry Error	michelle saemann (b) (4)	24 Mar 2021 12:53:44
User entered '3 Dec 2014'	Angela Snyder (b) (4)	23 Mar 2021 15:53:35

US3662116
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 09:24:58
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	16 Apr 2021 19:05:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:58:08
User entered '0'	Angela Snyder (b) (4) (b) (4)	23 Mar 2021 15:53:35

US3662116
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 09:24:58
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:58:08
User entered 'No (N)' reason for change: Data Entry Error	michelle saemann (b) (4)	24 Mar 2021 12:53:44
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	23 Mar 2021 15:59:50
User entered 'Yes (Y)' reason for change: Data Entry Error	Angela Snyder (b) (4)	23 Mar 2021 15:59:50
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	23 Mar 2021 15:59:42
User entered 'No (N)'	Angela Snyder (b) (4)	23 Mar 2021 15:53:35

US3662116
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 09:24:58
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:58:08
User entered '03 Feb 2015' reason for change: Data Entry Error	michelle saemann (b) (4)	24 Mar 2021 12:53:44
User closed query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	23 Mar 2021 15:59:42
User entered empty; reason for change Data Entry Error	Angela Snyder (b) (4)	23 Mar 2021 15:59:42
User opened query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	23 Mar 2021 15:53:35
User entered '6 Oct 2014'	Angela Snyder (b) (4)	23 Mar 2021 15:53:35

US3662116
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 09:24:58
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	16 Apr 2021 19:05:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:58:08
User entered '0'	Angela Snyder (b) (4) (b) (4)	23 Mar 2021 15:53:35

US3662116
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 09:24:58
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered 'Apr 2014'	System	24 Mar 2021 12:53:44
User entered 'Dec 2014'	System	23 Mar 2021 15:53:35

US3662116
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 09:24:58
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered '2014'	System	23 Mar 2021 15:53:35

FDA-CBER-2022-1614-2918809

US3662116
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 09:24:58
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered 'Feb 2015'	System	24 Mar 2021 12:53:44
User entered empty.	System	23 Mar 2021 15:59:42
User entered 'Oct 2014'	System	23 Mar 2021 15:53:35

US3662116
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 09:24:58
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered '2015'	System	24 Mar 2021 12:53:44
User entered empty.	System	23 Mar 2021 15:59:42
User entered '2014'	System	23 Mar 2021 15:53:35

US3662116
Folder: Screening
Form: Medical History (11)
Generated On: 10 Jun 2021 09:24:58
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:58:08
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Pulmonary vascular disorders, HLT: Pulmonary thrombotic and embolic conditions, PT: Pulmonary embolism, LLT: Pulmonary embolism - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 06:51:28
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 06:51:28
Data point term sent to Coder	System	23 Mar 2021 16:01:56
User entered 'pulmonary embolism acute'	Angela Snyder (b) (4)	23 Mar 2021 16:01:04

US3662116
Folder: Screening
Form: Medical History (11)
Generated On: 10 Jun 2021 09:24:58
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	16 Apr 2021 19:05:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:58:08
User entered '11 May 2017'	Angela Snyder (b) (4) (b) (4)	23 Mar 2021 16:01:04

US3662116
Folder: Screening
Form: Medical History (11)
Generated On: 10 Jun 2021 09:24:58
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	16 Apr 2021 19:05:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:58:08
User entered '0'	Angela Snyder (b) (4) (b) (4)	23 Mar 2021 16:01:04

US3662116
Folder: Screening
Form: Medical History (11)
Generated On: 10 Jun 2021 09:24:58
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	16 Apr 2021 19:05:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:58:08
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	23 Mar 2021 16:01:04

US3662116
Folder: Screening
Form: Medical History (11)
Generated On: 10 Jun 2021 09:24:58
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	16 Apr 2021 19:05:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:58:08
User entered '9 May 2018'	Angela Snyder (b) (4) (b) (4)	23 Mar 2021 16:01:04

US3662116
Folder: Screening
Form: Medical History (11)
Generated On: 10 Jun 2021 09:24:58
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	16 Apr 2021 19:05:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:58:08
User entered '0'	Angela Snyder (b) (4) (b) (4)	23 Mar 2021 16:01:04

US3662116
Folder: Screening
Form: Medical History (11)
Generated On: 10 Jun 2021 09:24:58
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered 'May 2017'	System	23 Mar 2021 16:01:04

US3662116
Folder: Screening
Form: Medical History (11)
Generated On: 10 Jun 2021 09:24:58
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered '2017'	System	23 Mar 2021 16:01:04

FDA-CBER-2022-1614-2918819

US3662116
Folder: Screening
Form: Medical History (11)
Generated On: 10 Jun 2021 09:24:58
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered 'May 2018'	System	23 Mar 2021 16:01:04

FDA-CBER-2022-1614-2918820

US3662116
Folder: Screening
Form: Medical History (11)
Generated On: 10 Jun 2021 09:24:58
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered '2018'	System	23 Mar 2021 16:01:04

FDA-CBER-2022-1614-2918821

US3662116
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 09:24:58
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:54
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:06:30
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Procedural related injuries and complications NEC, HLT: Non-site specific procedural complications, PT: Incisional hernia, LLT: Incisional hernia without mention of obstruction or gangrene - version MedDRA\\23.0.	Coder Import (b) (4)	29 Mar 2021 13:43:13
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	29 Mar 2021 13:43:13
Data point term sent to Coder	System	25 Mar 2021 18:46:21
User entered 'incisional hernia without obstruction or gangrene'	michelle saemann (b) (4)	25 Mar 2021 18:45:37

US3662116
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 09:24:58
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	16 Apr 2021 19:05:54
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:06:30
User entered '13 Mar 2015'	michelle saemann (b) (4) (b) (4)	25 Mar 2021 18:45:37

US3662116
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 09:24:58
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	16 Apr 2021 19:05:54
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:06:30
User entered '0'	michelle saemann (b) (4) (b) (4)	25 Mar 2021 18:45:37

US3662116
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 09:24:58
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	16 Apr 2021 19:05:54
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:06:30
User entered 'Yes (Y)'	michelle saemann (b) (4) (b) (4)	25 Mar 2021 18:45:37

US3662116
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 09:24:58
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:54
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:06:30
User entered empty.	michelle saemann (b) (4)	25 Mar 2021 18:45:37

FDA-CBER-2022-1614-2918826

US3662116
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 09:24:58
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:54
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:06:30
User entered '0'	michelle saemann (b) (4)	25 Mar 2021 18:45:37

US3662116
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 09:24:58
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered 'Mar 2015'	System	25 Mar 2021 18:45:37

US3662116
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 09:24:58
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered '2015'	System	25 Mar 2021 18:45:37

FDA-CBER-2022-1614-2918829

US3662116
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 09:24:58
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered empty.	System	25 Mar 2021 18:45:37

US3662116
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 09:24:58
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered empty.	System	25 Mar 2021 18:45:37

FDA-CBER-2022-1614-2918831

US3662116
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 09:24:58
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	16 Apr 2021 19:05:54
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 Apr 2021 08:23:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Apr 2021 08:23:49
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:56:47
Data point term sent to Coder	System	07 Apr 2021 13:42:59
User closed query 'Per CDM Coding: for term CHOLECYSTECTOMY WITH PARTIAL HEPATECTOMY, Multiple medical concepts are reported. Please split and report each term on separate lines to capture coding for all the terms, e.g. one of CHOLECYSTECTOMY and one of PARTIAL HEPATECTOMY etc. ' (Site from System).	System	07 Apr 2021 13:42:47
Query 'Per CDM Coding: for term CHOLECYSTECTOMY WITH PARTIAL HEPATECTOMY, Multiple medical concepts are reported. Please split and report each term on separate lines to capture coding for all the terms, e.g. one of CHOLECYSTECTOMY and one of PARTIAL HEPATECTOMY etc. ' answered with 'this was one procedure, not 2 separate procedures. Will leave as entered. ' (Site from System).	michelle saemann (b) (4) (b) (4)	07 Apr 2021 13:42:47
User opened query 'Per CDM Coding: for term CHOLECYSTECTOMY WITH PARTIAL HEPATECTOMY, Multiple medical concepts are reported. Please split and report each term on separate lines to capture coding for all the terms, e.g. one of CHOLECYSTECTOMY and one of PARTIAL HEPATECTOMY etc. ' (Site from System).	Coder Import (b) (4) (b) (4)	06 Apr 2021 13:45:43
Data point term sent to Coder	System	06 Apr 2021 13:04:50

US3662116
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 09:24:58
Condition

Audit	User	Time (GMT)
User entered 'cholecystectomy with partial hepatectomy'	michelle saemann (b) (4) (b) (4)	06 Apr 2021 13:04:15

US3662116
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 09:24:58
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	16 Apr 2021 19:05:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:56:47
User entered '09 May 2014'	michelle saemann (b) (4) (b) (4)	06 Apr 2021 13:04:15

US3662116
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 09:24:58
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	16 Apr 2021 19:05:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:56:47
User entered '0'	michelle saemann (b) (4) (b) (4)	06 Apr 2021 13:04:15

US3662116
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 09:24:58
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	16 Apr 2021 19:05:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:56:47
User entered 'No (N)'	michelle saemann (b) (4) (b) (4)	06 Apr 2021 13:04:15

FDA-CBER-2022-1614-2918836

US3662116
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 09:24:58
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	16 Apr 2021 19:05:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:56:47
User entered '09 May 2014'	michelle saemann (b) (4) (b) (4)	06 Apr 2021 13:04:15

US3662116
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 09:24:58
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	16 Apr 2021 19:05:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 15:56:47
User entered '0'	michelle saemann (b) (4) (b) (4)	06 Apr 2021 13:04:15

US3662116
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 09:24:58
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered 'May 2014'	System	06 Apr 2021 13:04:15

FDA-CBER-2022-1614-2918839

US3662116
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 09:24:58
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered '2014'	System	06 Apr 2021 13:04:15

FDA-CBER-2022-1614-2918840

US3662116
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 09:24:58
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered 'May 2014'	System	06 Apr 2021 13:04:15

FDA-CBER-2022-1614-2918841

US3662116
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 09:24:58
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered '2014'	System	06 Apr 2021 13:04:15

FDA-CBER-2022-1614-2918842

US3662116
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 09:24:58
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	16 Apr 2021 19:05:54
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:08:48
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Herpes simplex, LLT: Herpes simplex type II - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Apr 2021 18:38:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Apr 2021 18:38:43
Data point term sent to Coder	System	07 Apr 2021 18:37:10
User entered 'herpes simplex virus 2'	Angela Snyder (b) (4) (b) (4)	07 Apr 2021 18:36:19

US3662116
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 09:24:58
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	16 Apr 2021 19:05:54
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:08:48
User entered '11 Jan 2019'	Angela Snyder (b) (4) (b) (4)	07 Apr 2021 18:36:19

US3662116
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 09:24:58
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	16 Apr 2021 19:05:54
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:08:48
User entered '0'	Angela Snyder (b) (4) (b) (4)	07 Apr 2021 18:36:19

US3662116
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 09:24:58
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	16 Apr 2021 19:05:54
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:08:48
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	07 Apr 2021 18:36:19

US3662116
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 09:24:58
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	16 Apr 2021 19:05:54
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:08:48
User entered empty.	Angela Snyder (b) (4) (b) (4)	07 Apr 2021 18:36:19

US3662116
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 09:24:58
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	16 Apr 2021 19:05:54
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:08:48
User entered '0'	Angela Snyder (b) (4) (b) (4)	07 Apr 2021 18:36:19

US3662116
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 09:24:58
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered 'Jan 2019'	System	07 Apr 2021 18:36:19

US3662116
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 09:24:58
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered '2019'	System	07 Apr 2021 18:36:19

FDA-CBER-2022-1614-2918850

US3662116
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 09:24:58
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered empty.	System	07 Apr 2021 18:36:19

US3662116
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 09:24:58
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered empty.	System	07 Apr 2021 18:36:19

FDA-CBER-2022-1614-2918852

US3662116
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 09:24:58
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:54
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:08:55
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety state, unspecified - version MedDRA\\23.0.	Coder Import (b) (4)	08 Apr 2021 05:36:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	08 Apr 2021 05:36:40
Data point term sent to Coder	System	07 Apr 2021 18:37:10
User entered 'anxiety state unspecified'	Angela Snyder (b) (4)	07 Apr 2021 18:36:56

FDA-CBER-2022-1614-2918853

US3662116
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 09:24:58
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4)	16 Apr 2021 19:05:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:49:36
User closed query 'Per source is 25-Jan-2016. Please verify and update. ' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 21:25:46
Query 'Per source is 25-Jan-2016. Please verify and update. ' answered with 'Data updated' (Site from CRA).	Angela Snyder (b) (4) (b) (4)	09 Apr 2021 13:03:48
User entered '25 Jan 2016' reason for change: Data Entry Error	Angela Snyder (b) (4) (b) (4)	09 Apr 2021 13:03:25
DataPoint Un-verified.	(b) (4), (b) (6)	08 Apr 2021 17:09:05
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:08:55
User opened query 'Per source is 25-Jan-2016. Please verify and update. ' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 17:08:16
User entered '25 Jan 2019'	Angela Snyder (b) (4) (b) (4)	07 Apr 2021 18:36:56

FDA-CBER-2022-1614-2918854

US3662116
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 09:24:58
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	16 Apr 2021 19:05:54
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:08:55
User entered '0'	Angela Snyder (b) (4) (b) (4)	07 Apr 2021 18:36:56

US3662116
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 09:24:58
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	16 Apr 2021 19:05:54
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:08:55
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	07 Apr 2021 18:36:56

US3662116
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 09:24:58
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	16 Apr 2021 19:05:54
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:08:55
User entered empty.	Angela Snyder (b) (4) (b) (4)	07 Apr 2021 18:36:56

US3662116
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 09:24:58
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	16 Apr 2021 19:05:54
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:08:55
User entered '0'	Angela Snyder (b) (4) (b) (4)	07 Apr 2021 18:36:56

US3662116
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 09:24:58
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered 'Jan 2016'	System	09 Apr 2021 13:03:25
User entered 'Jan 2019'	System	07 Apr 2021 18:36:56

US3662116
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 09:24:58
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered '2016'	System	09 Apr 2021 13:03:25
User entered '2019'	System	07 Apr 2021 18:36:56

FDA-CBER-2022-1614-2918860

US3662116
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 09:24:58
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered empty.	System	07 Apr 2021 18:36:56

US3662116
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 09:24:58
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered empty.	System	07 Apr 2021 18:36:56

FDA-CBER-2022-1614-2918862

US3662116
Folder: Screening
Form: Medical History (16)
Generated On: 10 Jun 2021 09:24:58
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	16 Apr 2021 19:05:54
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:08:52
User coded data point as SOC: Psychiatric disorders, HLGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Apr 2021 18:39:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Apr 2021 18:39:47
Data point term sent to Coder	System	07 Apr 2021 18:38:12
User entered 'insomnia'	Angela Snyder (b) (4) (b) (4)	07 Apr 2021 18:37:29

US3662116
Folder: Screening
Form: Medical History (16)
Generated On: 10 Jun 2021 09:24:58
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	16 Apr 2021 19:05:54
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:08:52
User entered '25 Jan 2016'	Angela Snyder (b) (4) (b) (4)	07 Apr 2021 18:37:29

US3662116
Folder: Screening
Form: Medical History (16)
Generated On: 10 Jun 2021 09:24:58
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	16 Apr 2021 19:05:54
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:08:52
User entered '0'	Angela Snyder (b) (4) (b) (4)	07 Apr 2021 18:37:29

US3662116
Folder: Screening
Form: Medical History (16)
Generated On: 10 Jun 2021 09:24:58
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	16 Apr 2021 19:05:54
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:08:52
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	07 Apr 2021 18:37:29

US3662116
Folder: Screening
Form: Medical History (16)
Generated On: 10 Jun 2021 09:24:58
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	16 Apr 2021 19:05:54
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:08:52
User entered empty.	Angela Snyder (b) (4) (b) (4)	07 Apr 2021 18:37:29

US3662116
Folder: Screening
Form: Medical History (16)
Generated On: 10 Jun 2021 09:24:58
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	16 Apr 2021 19:05:54
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:08:52
User entered '0'	Angela Snyder (b) (4) (b) (4)	07 Apr 2021 18:37:29

US3662116
Folder: Screening
Form: Medical History (16)
Generated On: 10 Jun 2021 09:24:58
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered 'Jan 2016'	System	07 Apr 2021 18:37:29

US3662116
Folder: Screening
Form: Medical History (16)
Generated On: 10 Jun 2021 09:24:58
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered '2016'	System	07 Apr 2021 18:37:29

FDA-CBER-2022-1614-2918870

US3662116
Folder: Screening
Form: Medical History (16)
Generated On: 10 Jun 2021 09:24:58
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered empty.	System	07 Apr 2021 18:37:29

US3662116
Folder: Screening
Form: Medical History (16)
Generated On: 10 Jun 2021 09:24:58
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered empty.	System	07 Apr 2021 18:37:29

FDA-CBER-2022-1614-2918872

US3662116
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:58
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:40:22
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:05:09

US3662116
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:58
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:40:22
User entered '18 Sep 2020'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:05:09

US3662116
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:58
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:40:22
User entered '08:48'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:05:09

US3662116
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:58
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered '18 Sep 2020 08:48'	System	22 Sep 2020 14:05:09

US3662116
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:58
Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 13:40:22
User entered '153' cm	Brenda Miller (b) (4)	22 Sep 2020 14:05:09
DataPoint set to visible.	(b) (4) System	18 Sep 2020 13:02:50

US3662116
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:58
Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:40:22
User entered '119.3' kg	Brenda Miller (b) (4)	22 Sep 2020 14:05:09
DataPoint set to visible.	System	18 Sep 2020 13:02:50

US3662116
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:58
BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered '50.96330'	System	22 Sep 2020 14:05:09
DataPoint set to visible.	System	18 Sep 2020 13:02:50

US3662116
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:58
BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered 'kg/m2'	System	22 Sep 2020 14:05:09
DataPoint set to visible.	System	18 Sep 2020 13:02:50

US3662116
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:58
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:40:22
User entered missing code ND - Not Done.	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:05:09

US3662116
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:58
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:40:22
User entered empty.	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:05:09

US3662116
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:58
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:40:22
User entered empty.	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:05:09

US3662116
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:58
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:40:22
User entered missing code ND - Not Done.	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:05:09

US3662116
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:58
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered 'bpm'	System	22 Sep 2020 14:05:09

FDA-CBER-2022-1614-2918885

US3662116
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:58
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:40:22
User entered missing code ND - Not Done.	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:05:09

US3662116
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:58
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered 'breaths/min'	System	22 Sep 2020 14:05:09

FDA-CBER-2022-1614-2918887

US3662116
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:58
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:40:22
User entered missing code ND - Not Done.	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:05:09

US3662116
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:58
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered 'mmHg'	System	22 Sep 2020 14:05:09

FDA-CBER-2022-1614-2918889

US3662116
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:58
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:40:22
User entered missing code ND - Not Done.	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:05:09

US3662116
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:58
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered 'mmHg'	System	22 Sep 2020 14:05:09

FDA-CBER-2022-1614-2918891

US3662116
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:58
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05

FDA-CBER-2022-1614-2918892

US3662116
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:58
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05

FDA-CBER-2022-1614-2918893

US3662116
Folder: Screening
Form: Physical Examination
Generated On: 10 Jun 2021 09:24:58
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:40:27
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:05:22

US3662116
Folder: Screening
Form: Physical Examination
Generated On: 10 Jun 2021 09:24:58
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:40:27
User entered '18 Sep 2020'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:05:22

US3662116
Folder: Screening
Form: Childbearing Potential
Generated On: 10 Jun 2021 09:24:58
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:41:31
User entered '18 Sep 2020'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:06:28

US3662116
Folder: Screening
Form: Childbearing Potential
Generated On: 10 Jun 2021 09:24:58
Is the participant of childbearing potential?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:41:31
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:06:28

US3662116
Folder: Screening
Form: Childbearing Potential
Generated On: 10 Jun 2021 09:24:58
If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User closed query 'Per CDM Re-Query: Please note that Surgical Procedures are part of the subject's Medical History. If Surgical Procedures is confirmed, please add to the MH CRF. Thank you' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 10:19:11
Query 'Per CDM Re-Query: Please note that Surgical Procedures are part of the subject's Medical History. If Surgical Procedures is confirmed, please add to the MH CRF. Thank you' answered with 'Added hysterectomy to MH CRF' (Site from DM).	Brenda Miller (b) (4) (b) (4)	26 Oct 2020 13:41:15
User opened query 'Per CDM Re-Query: Please note that Surgical Procedures are part of the subject's Medical History. If Surgical Procedures is confirmed, please add to the MH CRF. Thank you' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 21:42:13
User closed query 'Per DM CLR: Note, "If No, what is the reason?" = Surgically sterile and Hysterectomy is recorded in MH; however associated condition with this surgery is not recorded as an MH condition. Ensure associated condition is recorded. Review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 21:42:13
Query 'Per DM CLR: Note, "If No, what is the reason?" = Surgically sterile and Hysterectomy is recorded in MH; however associated condition with this surgery is not recorded as an MH condition. Ensure associated condition is recorded. Review and update as appropriate. ' answered with 'NCS, PER PI' (Site from DM).	Brenda Miller (b) (4) (b) (4)	12 Oct 2020 12:44:36
Query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with this procedure in MH ecrf if applicable. Revew and update as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 07:55:00

US3662116
Folder: Screening
Form: Childbearing Potential
Generated On: 10 Jun 2021 09:24:58
If No, what is the reason?

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with this procedure in MH ecrf if applicable. Revew and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 07:54:58
User opened query 'Per DM CLR: Note, "If No, what is the reason?" = Surgically sterile and Hysterectomy is recorded in MH; however associated condition with this surgery is not recorded as an MH condition. Ensure associated condition is recorded. Review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 06:41:42
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:41:31
User entered 'Surgically sterile (SURGICALLY STERILE)'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:06:28

US3662116
Folder: Screening
Form: Childbearing Potential
Generated On: 10 Jun 2021 09:24:58
If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:41:31
User entered empty.	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:06:28

US3662116
Folder: Screening
Form: Childbearing Potential
Generated On: 10 Jun 2021 09:24:58
If Surgically sterile, date of surgery *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:57:02
DataPoint Un-verified.	michelle saemann (b) (4) (b) (4)	03 Nov 2020 21:16:11
User entered '31 May 2018' reason for change: Data Entry Error	michelle saemann (b) (4) (b) (4)	03 Nov 2020 21:16:11
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:41:31
User entered '01 Jul 2005'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:06:28

US3662116
Folder: Screening
Form: Childbearing Potential
Generated On: 10 Jun 2021 09:24:58
Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:41:31
User entered '0'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:06:28

US3662116
Folder: Screening
Form: Childbearing Potential
Generated On: 10 Jun 2021 09:24:58
If Post-menopausal, date of last menstruation *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:41:31
User entered empty.	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:06:28

US3662116
Folder: Screening
Form: Childbearing Potential
Generated On: 10 Jun 2021 09:24:58
Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:41:31
User entered '0'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:06:28

US3662116
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:24:58
Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:42:14
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:07:31

US3662116
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:24:58
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:42:14
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:07:31

US3662116
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:24:58
Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:42:14
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:07:31

US3662116
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:24:58
Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:42:14
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:07:31

US3662116
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:24:58
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:42:14
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:07:31

US3662116
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:24:58
Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:42:14
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:07:31

US3662116
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:24:58
Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:42:14
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:07:31

US3662116
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:24:58
Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:42:14
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:07:31

US3662116
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:24:58
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:42:14
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:07:31

US3662116
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:24:58
Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:42:14
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:07:31

US3662116
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:24:58
Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:42:14
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:07:31

US3662116
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:24:58
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:42:14
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:07:31

US3662116
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:24:58
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:42:14
User entered empty.	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:07:31

US3662116
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:24:58
No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:07:31

US3662116
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:24:58
Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:42:14
User entered '0'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:07:31

US3662116
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:24:58
Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:42:14
User entered '0'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:07:31

US3662116
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:24:58
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:42:14
User entered '1'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:07:31

US3662116
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:24:58
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:42:14
User entered '0'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:07:31

US3662116
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:24:58
Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:42:14
User entered '0'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:07:31

US3662116
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:24:58
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:07:31

US3662116
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:24:58
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:42:14
User entered empty.	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:07:31

US3662116
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 09:24:58
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:42:22
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:08:02

US3662116
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 09:24:58
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:42:22
User entered '18 Sep 2020'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:08:02

US3662116
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 09:24:58
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:42:22
User entered 'Clinic (Clinic)'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:08:02

US3662116
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 09:24:58
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User entered 'VISIT1'	System	22 Sep 2020 14:08:02

FDA-CBER-2022-1614-2918929

US3662116
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:24:58
What was the date of randomization? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:42:35
User entered '18 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	18 Sep 2020 13:24:21

FDA-CBER-2022-1614-2918930

US3662116
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:24:58
What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:42:35
User entered '146331'	RWS_ENDPOINT ENDPOINT (b) (4)	18 Sep 2020 13:24:21

US3662116
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:24:58
In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:42:35
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	18 Sep 2020 13:24:21

FDA-CBER-2022-1614-2918932

US3662116
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:24:58
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)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:42:35
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:08:43

US3662116
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:24:58

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)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:42:35
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:08:43

US3662116
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:24:58
Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:42:35
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:08:43

US3662116
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:24:58
Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:42:35
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:08:43

FDA-CBER-2022-1614-2918936

US3662116
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:24:58
Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:42:35
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:08:43

US3662116
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:24:58
Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:42:35
User entered 'No (N)'	Brenda Miller (b) (4)	22 Sep 2020 14:08:43
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 09:29:16
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 09:29:14

US3662116
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:24:58
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:55:44
User entered missing code ND - Not Done.	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:10:28

FDA-CBER-2022-1614-2918939

US3662116
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:24:58
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:55:44
User entered missing code ND - Not Done.	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:10:28

US3662116
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:24:58
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:55:44
User entered missing code ND - Not Done.	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:10:28

FDA-CBER-2022-1614-2918941

US3662116
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:24:58
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:55:44
User entered missing code ND - Not Done.	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:10:28

US3662116
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:24:58
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User accepted default value 'Pre-Dose (PREDOSE)'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:10:28

US3662116
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:24:58
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:54:34
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:10:28

US3662116
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:24:58
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:54:35
User entered '18 Sep 2020'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:10:28

US3662116
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:24:58
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:54:37
User entered '08:48'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:10:28

US3662116
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:24:58
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User entered '18 Sep 2020 08:48'	System	22 Sep 2020 14:10:28

FDA-CBER-2022-1614-2918947

US3662116
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:24:58
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:54:39
User entered '97.3' F	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:10:28

US3662116
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:24:58
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:54:40
User entered 'Other (Other)'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:10:28

US3662116
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:24:58
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:54:46
User entered 'INFRARED THERMOMETER' reason for change: Data Entry Error	Brenda Miller (b) (4) (b) (4)	24 Sep 2020 00:46:48
User entered 'TEMPORAL'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:10:28

US3662116
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:24:58
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:54:48
User entered '93'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:10:28

US3662116
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:24:58
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User entered 'bpm'	System	22 Sep 2020 14:10:28

FDA-CBER-2022-1614-2918952

US3662116
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:24:58
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:54:50
User entered '16'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:10:28

US3662116
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:24:58
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User entered 'breaths/min'	System	22 Sep 2020 14:10:28

FDA-CBER-2022-1614-2918954

US3662116
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:24:58
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:54:52
User entered '114'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:10:28

US3662116
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:24:58
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User entered 'mmHg'	System	22 Sep 2020 14:10:28

FDA-CBER-2022-1614-2918956

US3662116
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:24:58
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:54:53
User entered '83'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:10:28

US3662116
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:24:58
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User entered 'mmHg'	System	22 Sep 2020 14:10:28

FDA-CBER-2022-1614-2918958

US3662116
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:24:58
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:55:44
User entered missing code ND - Not Done.	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:10:28

FDA-CBER-2022-1614-2918959

US3662116
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:24:58
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:55:44
User entered missing code ND - Not Done.	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:10:28

US3662116
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:24:58
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User accepted default value 'Post-Dose (POSTDOSE)'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:10:28

FDA-CBER-2022-1614-2918961

US3662116
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:24:58
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User closed query 'Vital signs are prior to Dose - per source dose given at 10:17. Please confirm. If confirmed, please update all post-dose vitals to Not Done and dcument protocol deviation' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:54:50
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:54:47
Query 'Vital signs are prior to Dose - per source dose given at 10:17. Please confirm. If confirmed, please update all post-dose vitals to Not Done and dcument protocol deviation' answered with 'resolved' (Site from CRA).	michelle saemann (b) (4) (b) (4)	29 Sep 2020 15:39:26
User opened query 'Vital signs are prior to Dose - per source dose given at 10:17. Please confirm. If confirmed, please update all post-dose vitals to Not Done and dcument protocol deviation' (Site from CRA).	(b) (4), (b) (6)	29 Sep 2020 13:53:36
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:10:28

US3662116
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:24:58
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:55:44
User entered '18 Sep 2020'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:10:28

US3662116
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:24:58
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:55:44
User entered '10:48' reason for change: Data Entry Error	michelle saemann (b) (4) (b) (4)	29 Sep 2020 15:39:20
User entered '09:48'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:10:28

US3662116
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:24:58
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User entered '18 Sep 2020 10:48'	System	29 Sep 2020 15:39:20
User entered '18 Sep 2020 09:48'	System	22 Sep 2020 14:10:28

US3662116
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:24:58
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:55:44
User entered '98.0' F	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:10:28

US3662116
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:24:58
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:55:44
User entered 'Other (Other)'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:10:28

US3662116
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:24:58
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:55:44
User entered 'INFRARED THERMOMETER' reason for change: Data Entry Error	Brenda Miller (b) (4) (b) (4)	24 Sep 2020 00:46:48
User entered 'TEMPORAL'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:10:28

US3662116
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:24:58
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:55:44
User entered '91'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:10:28

US3662116
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:24:58
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User entered 'bpm'	System	22 Sep 2020 14:10:28

FDA-CBER-2022-1614-2918970

US3662116
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:24:58
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:55:44
User entered '12'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:10:28

FDA-CBER-2022-1614-2918971

US3662116
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:24:58
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User entered 'breaths/min'	System	22 Sep 2020 14:10:28

FDA-CBER-2022-1614-2918972

US3662116
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:24:58
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:55:44
User entered '122'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:10:28

US3662116
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:24:58
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User entered 'mmHg'	System	22 Sep 2020 14:10:28

FDA-CBER-2022-1614-2918974

US3662116
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:24:58
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:55:44
User entered '81'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:10:28

US3662116
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:24:58
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User entered 'mmHg'	System	22 Sep 2020 14:10:28

FDA-CBER-2022-1614-2918976

US3662116
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 10 Jun 2021 09:24:58
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:55:01
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:10:36

US3662116
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 10 Jun 2021 09:24:58
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:55:01
User entered empty.	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:10:36

US3662116
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:24:58
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:55:12
User entered 'Yes (Y)'	michelle saemann (b) (4) (b) (4)	18 Sep 2020 14:21:32

US3662116
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:24:58
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:55:12
User entered empty.	michelle saemann (b) (4) (b) (4)	18 Sep 2020 14:21:32

US3662116
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:24:58
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)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:55:12
User entered empty.	michelle saemann (b) (4) (b) (4)	18 Sep 2020 14:21:32

US3662116
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:24:58
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User entered 'MRNA-1273 OR PLACEBO'	System	18 Sep 2020 14:21:32

FDA-CBER-2022-1614-2918982

US3662116
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:24:58
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:55:12
User entered '18 Sep 2020'	michelle saemann (b) (4) (b) (4)	18 Sep 2020 14:21:32

US3662116
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:24:58
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:55:12
User entered '10:17'	michelle saemann (b) (4) (b) (4)	18 Sep 2020 14:21:32

US3662116
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:24:58
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User entered '18 Sep 2020 10:17'	System	18 Sep 2020 14:21:32

FDA-CBER-2022-1614-2918985

US3662116
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:24:58
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:55:12
User entered 'Left Arm (LEFT ARM)'	michelle saemann (b) (4)	18 Sep 2020 14:21:32

US3662116
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:24:58
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:55:12
User entered 'ONCE'	System	18 Sep 2020 14:21:32

US3662116
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:24:58
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User entered 'INTRAMUSCULAR'	System	18 Sep 2020 14:21:32

US3662116
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:24:58
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:55:39
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:11:31

US3662116
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:24:58
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:55:40
User entered '18 Sep 2020'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:11:31

US3662116
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:24:58
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:55:42
User entered '09:25'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:11:31

US3662116
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:24:58
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User entered '18 Sep 2020 09:25'	System	22 Sep 2020 14:11:31

US3662116
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 10 Jun 2021 09:24:58
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:55:53
User entered '18 Sep 2020'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:11:51

US3662116
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:24:58
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:11:51

US3662116
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:24:58
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:55:53
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:11:51

US3662116
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:24:58
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:55:53
User entered '09:20'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:11:51

US3662116
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:24:58
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User entered '18 Sep 2020 09:20'	System	22 Sep 2020 14:11:51

US3662116
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:24:58
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:11:51

US3662116
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:24:58
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:55:53
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:11:51

US3662116
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:24:58
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:55:53
User entered empty.	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:11:51

US3662116
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:24:58
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User entered empty.	System	22 Sep 2020 14:11:51

US3662116
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 10 Jun 2021 09:24:58
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:56:05
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	25 Sep 2020 15:27:23

US3662116
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 10 Jun 2021 09:24:58
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User entered '1'	System	25 Sep 2020 15:27:23

FDA-CBER-2022-1614-2919003

US3662116
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
Data entry locked.	System	18 Sep 2020 14:21:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 14:21:32

US3662116
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:24:58
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-18T10:48:52', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'ad166aed-3fd0-4a5c-a98f-2dc77af5f970'	System	18 Sep 2020 14:49:11
User entered 'Yes (Y)'	System	18 Sep 2020 14:49:11

FDA-CBER-2022-1614-2919005

US3662116
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:24:58
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-18T10:48:58', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'ad166aed-3fd0-4a5c-a98f-2dc77af5f970'	System	18 Sep 2020 14:49:11
User entered '98.0'	System	18 Sep 2020 14:49:11

US3662116
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:24:58
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-18T10:49:04', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'ad166aed-3fd0-4a5c-a98f-2dc77af5f970'	System	18 Sep 2020 14:49:11
User entered 'No (N)'	System	18 Sep 2020 14:49:11

US3662116
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:24:58
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-18T10:49:08', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'ad166aed-3fd0-4a5c-a98f-2dc77af5f970'	System	18 Sep 2020 14:49:11
User entered '18 Sep 2020 10:49'	System	18 Sep 2020 14:49:11

US3662116
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:24:58
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '18 Sep 2020 10:37'	System	18 Sep 2020 14:21:32

FDA-CBER-2022-1614-2919009

US3662116
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:24:58
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '18 Sep 2020 13:07'	System	18 Sep 2020 14:21:32

FDA-CBER-2022-1614-2919010

US3662116
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
Data entry locked.	System	18 Sep 2020 14:21:32
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 14:21:32

US3662116
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:24:58
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-18T17:10:05', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '1fe4ef77-a736-4ab1-a07e-22f15c2e538c'	System	18 Sep 2020 21:10:24
User entered 'Yes (Y)'	System	18 Sep 2020 21:10:24

FDA-CBER-2022-1614-2919012

US3662116
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:24:58
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-18T17:10:12', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '1fe4ef77-a736-4ab1-a07e-22f15c2e538c'	System	18 Sep 2020 21:10:24
User entered '98.0'	System	18 Sep 2020 21:10:24

US3662116
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:24:58
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-18T17:10:17', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '1fe4ef77-a736-4ab1-a07e-22f15c2e538c'	System	18 Sep 2020 21:10:24
User entered 'No (N)'	System	18 Sep 2020 21:10:24

US3662116
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:24:58
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-18T17:10:22', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '1fe4ef77-a736-4ab1-a07e-22f15c2e538c'	System	18 Sep 2020 21:10:24
User entered '18 Sep 2020 17:10'	System	18 Sep 2020 21:10:24

FDA-CBER-2022-1614-2919015

US3662116
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:24:58
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '18 Sep 2020 14:02'	System	18 Sep 2020 14:21:32

FDA-CBER-2022-1614-2919016

US3662116
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:24:58
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 14:21:32

FDA-CBER-2022-1614-2919017

US3662116
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
Data entry locked.	System	18 Sep 2020 14:21:32
User entered 'Day 2'	System	18 Sep 2020 14:21:32

US3662116
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:24:58
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-19T17:03:59', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'd7c8479b-aed0-4249-aa78-1fc878423f55'	System	19 Sep 2020 21:04:17
User entered 'Yes (Y)'	System	19 Sep 2020 21:04:17

FDA-CBER-2022-1614-2919019

US3662116
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:24:58
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-19T17:04:06', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'd7c8479b-aed0-4249-aa78-1fc878423f55'	System	19 Sep 2020 21:04:17
User entered '98.2'	System	19 Sep 2020 21:04:17

US3662116
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:24:58
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-19T17:04:12', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'd7c8479b-aed0-4249-aa78-1fc878423f55'	System	19 Sep 2020 21:04:17
User entered 'No (N)'	System	19 Sep 2020 21:04:17

US3662116
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:24:58
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-19T17:04:15', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'd7c8479b-aed0-4249-aa78-1fc878423f55'	System	19 Sep 2020 21:04:17
User entered '19 Sep 2020 17:04'	System	19 Sep 2020 21:04:17

US3662116
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:24:58
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 14:21:32

FDA-CBER-2022-1614-2919023

US3662116
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:24:58
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 14:21:32

FDA-CBER-2022-1614-2919024

US3662116
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
Data entry locked.	System	18 Sep 2020 14:21:32
User entered 'Day 3'	System	18 Sep 2020 14:21:32

US3662116
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:24:58
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-20T12:24:09', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'a0b31835-8e8e-4b8f-9bac-b0679408ec94'	System	20 Sep 2020 16:24:34
User entered 'Yes (Y)'	System	20 Sep 2020 16:24:34

FDA-CBER-2022-1614-2919026

US3662116
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:24:58
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-20T12:24:16', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'a0b31835-8e8e-4b8f-9bac-b0679408ec94'	System	20 Sep 2020 16:24:34
User entered '98.2'	System	20 Sep 2020 16:24:34

US3662116
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:24:58
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-20T12:24:25', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'a0b31835-8e8e-4b8f-9bac-b0679408ec94'	System	20 Sep 2020 16:24:34
User entered 'No (N)'	System	20 Sep 2020 16:24:34

US3662116
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:24:58
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-20T12:24:30', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'a0b31835-8e8e-4b8f-9bac-b0679408ec94'	System	20 Sep 2020 16:24:34
User entered '20 Sep 2020 12:24'	System	20 Sep 2020 16:24:34

US3662116
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:24:58
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 14:21:32

FDA-CBER-2022-1614-2919030

US3662116
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:24:58
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 14:21:32

FDA-CBER-2022-1614-2919031

US3662116
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
Data entry locked.	System	18 Sep 2020 14:21:32
User entered 'Day 4'	System	18 Sep 2020 14:21:32

US3662116
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:24:58
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-21T17:29:41', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'e25684a8-d874-472a-84a2-8c935ddbfa58'	System	21 Sep 2020 21:30:04
User entered 'Yes (Y)'	System	21 Sep 2020 21:30:04

FDA-CBER-2022-1614-2919033

US3662116
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:24:58
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-21T17:29:52', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'e25684a8-d874-472a-84a2-8c935ddbfa58'	System	21 Sep 2020 21:30:04
User entered '98.0'	System	21 Sep 2020 21:30:04

FDA-CBER-2022-1614-2919034

US3662116
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:24:58
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-21T17:29:56', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'e25684a8-d874-472a-84a2-8c935ddbfa58'	System	21 Sep 2020 21:30:04
User entered 'No (N)'	System	21 Sep 2020 21:30:04

FDA-CBER-2022-1614-2919035

US3662116
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:24:58
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-21T17:30:00', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'e25684a8-d874-472a-84a2-8c935ddbfa58'	System	21 Sep 2020 21:30:04
User entered '21 Sep 2020 17:30'	System	21 Sep 2020 21:30:04

FDA-CBER-2022-1614-2919036

US3662116
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:24:58
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 14:21:32

FDA-CBER-2022-1614-2919037

US3662116
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:24:58
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 14:21:32

FDA-CBER-2022-1614-2919038

US3662116
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
Data entry locked.	System	18 Sep 2020 14:21:32
User entered 'Day 5'	System	18 Sep 2020 14:21:32

US3662116
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:24:58
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-22T16:33:55', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'f44c92bd-50e5-4201-bc2d-ee56c1ec5b90'	System	22 Sep 2020 20:35:25
User entered 'Yes (Y)'	System	22 Sep 2020 20:35:25

US3662116
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:24:58
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-22T16:34:52', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'f44c92bd-50e5-4201-bc2d-ee56c1ec5b90'	System	22 Sep 2020 20:35:25
User entered '98.0'	System	22 Sep 2020 20:35:25

FDA-CBER-2022-1614-2919041

US3662116
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:24:58
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-22T16:35:19', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'f44c92bd-50e5-4201-bc2d-ee56c1ec5b90'	System	22 Sep 2020 20:35:25
User entered 'No (N)'	System	22 Sep 2020 20:35:25

US3662116
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:24:58
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-22T16:35:21', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'f44c92bd-50e5-4201-bc2d-ee56c1ec5b90'	System	22 Sep 2020 20:35:25
User entered '22 Sep 2020 16:35'	System	22 Sep 2020 20:35:25

US3662116
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:24:58
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 14:21:32

FDA-CBER-2022-1614-2919044

US3662116
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:24:58
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 14:21:32

FDA-CBER-2022-1614-2919045

US3662116
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
Data entry locked.	System	18 Sep 2020 14:21:32
User entered 'Day 6'	System	18 Sep 2020 14:21:32

US3662116
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:24:58
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-23T16:03:44', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '9d4aa9c4-a35c-4e40-ac13-ed073109a8bd'	System	23 Sep 2020 20:03:55
User entered 'Yes (Y)'	System	23 Sep 2020 20:03:55

FDA-CBER-2022-1614-2919047

US3662116
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:24:58
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-23T16:03:49', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '9d4aa9c4-a35c-4e40-ac13-ed073109a8bd'	System	23 Sep 2020 20:03:55
User entered '98.2'	System	23 Sep 2020 20:03:55

US3662116
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:24:58
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-23T16:03:52', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '9d4aa9c4-a35c-4e40-ac13-ed073109a8bd'	System	23 Sep 2020 20:03:55
User entered 'No (N)'	System	23 Sep 2020 20:03:55

US3662116
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:24:58
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-23T16:03:54', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '9d4aa9c4-a35c-4e40-ac13-ed073109a8bd'	System	23 Sep 2020 20:03:55
User entered '23 Sep 2020 16:03'	System	23 Sep 2020 20:03:55

FDA-CBER-2022-1614-2919050

US3662116
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:24:58
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 14:21:32

FDA-CBER-2022-1614-2919051

US3662116
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:24:58
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 14:21:32

FDA-CBER-2022-1614-2919052

US3662116
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
Data entry locked.	System	18 Sep 2020 14:21:32
User entered 'Day 7'	System	18 Sep 2020 14:21:32

US3662116
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:24:58
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-24T13:39:14', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '9cf05d21-edc7-4050-bc4a-57b430710f21'	System	24 Sep 2020 17:39:36
User entered 'Yes (Y)'	System	24 Sep 2020 17:39:36

FDA-CBER-2022-1614-2919054

US3662116
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:24:58
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-24T13:39:26', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '9cf05d21-edc7-4050-bc4a-57b430710f21'	System	24 Sep 2020 17:39:36
User entered '97.9'	System	24 Sep 2020 17:39:36

FDA-CBER-2022-1614-2919055

US3662116
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:24:58
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-24T13:39:30', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '9cf05d21-edc7-4050-bc4a-57b430710f21'	System	24 Sep 2020 17:39:36
User entered 'No (N)'	System	24 Sep 2020 17:39:36

US3662116
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:24:58
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-24T13:39:33', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '9cf05d21-edc7-4050-bc4a-57b430710f21'	System	24 Sep 2020 17:39:36
User entered '24 Sep 2020 13:39'	System	24 Sep 2020 17:39:36

US3662116
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:24:58
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 14:21:32

FDA-CBER-2022-1614-2919058

US3662116
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:24:58
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 14:21:32

FDA-CBER-2022-1614-2919059

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
Data entry locked.	System	18 Sep 2020 14:21:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 14:21:32

FDA-CBER-2022-1614-2919060

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:24:58
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-18T10:47:16', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '8c82db5c-7c3f-46d7-a280-61280d64c2d6'	System	18 Sep 2020 14:48:39
User entered 'None (1)'	System	18 Sep 2020 14:48:39

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:24:58
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-18T10:47:46', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '8c82db5c-7c3f-46d7-a280-61280d64c2d6'	System	18 Sep 2020 14:48:39
User entered 'No (N)'	System	18 Sep 2020 14:48:39

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:24:58
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-18T10:47:50', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '8c82db5c-7c3f-46d7-a280-61280d64c2d6'	System	18 Sep 2020 14:48:39
User entered 'No (N)'	System	18 Sep 2020 14:48:39

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:24:58
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-18T10:48:29', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '8c82db5c-7c3f-46d7-a280-61280d64c2d6'	System	18 Sep 2020 14:48:39
User entered 'None (1)'	System	18 Sep 2020 14:48:39

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:24:58
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-18T10:48:36', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '8c82db5c-7c3f-46d7-a280-61280d64c2d6'	System	18 Sep 2020 14:48:39
User entered '18 Sep 2020 10:48'	System	18 Sep 2020 14:48:39

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:24:58
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '18 Sep 2020 10:37'	System	18 Sep 2020 14:21:32

FDA-CBER-2022-1614-2919066

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:24:58
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '18 Sep 2020 13:07'	System	18 Sep 2020 14:21:32

FDA-CBER-2022-1614-2919067

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
Data entry locked.	System	18 Sep 2020 14:21:32
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 14:21:32

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:24:58
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-18T17:09:17', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'cda9597e-4f86-4a0b-a8f7-cbfe7d01799b'	System	18 Sep 2020 21:09:56
User entered 'Does not interfere with activity (2)'	System	18 Sep 2020 21:09:56

FDA-CBER-2022-1614-2919069

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:24:58
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-18T17:09:21', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'cda9597e-4f86-4a0b-a8f7-cbfe7d01799b'	System	18 Sep 2020 21:09:56
User entered 'No (N)'	System	18 Sep 2020 21:09:56

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:24:58
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-18T17:09:31', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'cda9597e-4f86-4a0b-a8f7-cbfe7d01799b'	System	18 Sep 2020 21:09:56
User entered 'No (N)'	System	18 Sep 2020 21:09:56

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:24:58
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-18T17:09:42', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'cda9597e-4f86-4a0b-a8f7-cbfe7d01799b'	System	18 Sep 2020 21:09:56
User entered 'None (1)'	System	18 Sep 2020 21:09:56

FDA-CBER-2022-1614-2919072

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:24:58
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-18T17:09:52', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'cda9597e-4f86-4a0b-a8f7-cbfe7d01799b'	System	18 Sep 2020 21:09:56
User entered '18 Sep 2020 17:09'	System	18 Sep 2020 21:09:56

FDA-CBER-2022-1614-2919073

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:24:58
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '18 Sep 2020 14:02'	System	18 Sep 2020 14:21:32

FDA-CBER-2022-1614-2919074

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:24:58
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 14:21:32

FDA-CBER-2022-1614-2919075

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
Data entry locked.	System	18 Sep 2020 14:21:32
User entered 'Day 2'	System	18 Sep 2020 14:21:32

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:24:58
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-19T17:04:25', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '01b63c88-be2b-4462-8a08-41ceebb07324'	System	19 Sep 2020 21:04:49
User entered 'Does not interfere with activity (2)'	System	19 Sep 2020 21:04:49

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:24:58
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-19T17:04:28', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '01b63c88-be2b-4462-8a08-41ceebb07324'	System	19 Sep 2020 21:04:49
User entered 'No (N)'	System	19 Sep 2020 21:04:49

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:24:58
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-19T17:04:33', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '01b63c88-be2b-4462-8a08-41ceebb07324'	System	19 Sep 2020 21:04:49
User entered 'No (N)'	System	19 Sep 2020 21:04:49

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:24:58
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-19T17:04:44', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '01b63c88-be2b-4462-8a08-41ceebb07324'	System	19 Sep 2020 21:04:49
User entered 'None (1)'	System	19 Sep 2020 21:04:49

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:24:58
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-19T17:04:47', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '01b63c88-be2b-4462-8a08-41ceebb07324'	System	19 Sep 2020 21:04:49
User entered '19 Sep 2020 17:04'	System	19 Sep 2020 21:04:49

FDA-CBER-2022-1614-2919081

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:24:58
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 14:21:32

FDA-CBER-2022-1614-2919082

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:24:58
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 14:21:32

FDA-CBER-2022-1614-2919083

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
Data entry locked.	System	18 Sep 2020 14:21:32
User entered 'Day 3'	System	18 Sep 2020 14:21:32

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:24:58
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-20T12:24:41', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '4327fc7f-8a8c-4e75-a275-7a8c96a5761a'	System	20 Sep 2020 16:25:11
User entered 'Does not interfere with activity (2)'	System	20 Sep 2020 16:25:11

FDA-CBER-2022-1614-2919085

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:24:58
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-20T12:24:45', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '4327fc7f-8a8c-4e75-a275-7a8c96a5761a'	System	20 Sep 2020 16:25:11
User entered 'No (N)'	System	20 Sep 2020 16:25:11

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:24:58
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-20T12:24:51', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '4327fc7f-8a8c-4e75-a275-7a8c96a5761a'	System	20 Sep 2020 16:25:11
User entered 'No (N)'	System	20 Sep 2020 16:25:11

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:24:58
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-20T12:25:03', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '4327fc7f-8a8c-4e75-a275-7a8c96a5761a'	System	20 Sep 2020 16:25:11
User entered 'None (1)'	System	20 Sep 2020 16:25:11

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:24:58
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-20T12:25:07', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '4327fc7f-8a8c-4e75-a275-7a8c96a5761a'	System	20 Sep 2020 16:25:11
User entered '20 Sep 2020 12:25'	System	20 Sep 2020 16:25:11

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:24:58
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 14:21:32

FDA-CBER-2022-1614-2919090

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:24:58
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 14:21:32

FDA-CBER-2022-1614-2919091

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
Data entry locked.	System	18 Sep 2020 14:21:32
User entered 'Day 4'	System	18 Sep 2020 14:21:32

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:24:58
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-21T17:30:06', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'c5347157-2920-46a5-af16-2f8b00bbd717'	System	21 Sep 2020 21:30:27
User entered 'None (1)'	System	21 Sep 2020 21:30:27

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:24:58
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-21T17:30:09', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'c5347157-2920-46a5-af16-2f8b00bbd717'	System	21 Sep 2020 21:30:27
User entered 'No (N)'	System	21 Sep 2020 21:30:27

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:24:58
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-21T17:30:15', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'c5347157-2920-46a5-af16-2f8b00bbd717'	System	21 Sep 2020 21:30:27
User entered 'No (N)'	System	21 Sep 2020 21:30:27

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:24:58
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-21T17:30:20', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'c5347157-2920-46a5-af16-2f8b00bbd717'	System	21 Sep 2020 21:30:27
User entered 'None (1)'	System	21 Sep 2020 21:30:27

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:24:58
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-21T17:30:23', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'c5347157-2920-46a5-af16-2f8b00bbd717'	System	21 Sep 2020 21:30:27
User entered '21 Sep 2020 17:30'	System	21 Sep 2020 21:30:27

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:24:58
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 14:21:32

FDA-CBER-2022-1614-2919098

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:24:58
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 14:21:32

FDA-CBER-2022-1614-2919099

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
Data entry locked.	System	18 Sep 2020 14:21:32
User entered 'Day 5'	System	18 Sep 2020 14:21:32

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:24:58
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-22T23:13:08', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '7c39a090-00eb-4697-af70-fa8e5f2a7bf7'	System	23 Sep 2020 03:13:23
User entered 'None (1)'	System	23 Sep 2020 03:13:23

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:24:58
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-22T23:13:11', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '7c39a090-00eb-4697-af70-fa8e5f2a7bf7'	System	23 Sep 2020 03:13:23
User entered 'No (N)'	System	23 Sep 2020 03:13:23

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:24:58
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-22T23:13:15', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '7c39a090-00eb-4697-af70-fa8e5f2a7bf7'	System	23 Sep 2020 03:13:23
User entered 'No (N)'	System	23 Sep 2020 03:13:23

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:24:58
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-22T23:13:18', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '7c39a090-00eb-4697-af70-fa8e5f2a7bf7'	System	23 Sep 2020 03:13:23
User entered 'None (1)'	System	23 Sep 2020 03:13:23

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:24:58
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-22T23:13:21', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '7c39a090-00eb-4697-af70-fa8e5f2a7bf7'	System	23 Sep 2020 03:13:23
User entered '22 Sep 2020 23:13'	System	23 Sep 2020 03:13:23

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:24:58
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 14:21:32

FDA-CBER-2022-1614-2919106

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:24:58
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 14:21:32

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
Data entry locked.	System	18 Sep 2020 14:21:32
User entered 'Day 6'	System	18 Sep 2020 14:21:32

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:24:58
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-23T16:04:00', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'd3013341-71db-48c6-ac53-5757410d3201'	System	23 Sep 2020 20:04:24
User entered 'None (1)'	System	23 Sep 2020 20:04:24

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:24:58
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-23T16:04:04', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'd3013341-71db-48c6-ac53-5757410d3201'	System	23 Sep 2020 20:04:24
User entered 'No (N)'	System	23 Sep 2020 20:04:24

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:24:58
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-23T16:04:09', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'd3013341-71db-48c6-ac53-5757410d3201'	System	23 Sep 2020 20:04:24
User entered 'No (N)'	System	23 Sep 2020 20:04:24

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:24:58
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-23T16:04:18', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'd3013341-71db-48c6-ac53-5757410d3201'	System	23 Sep 2020 20:04:24
User entered 'None (1)'	System	23 Sep 2020 20:04:24

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:24:58
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-23T16:04:20', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'd3013341-71db-48c6-ac53-5757410d3201'	System	23 Sep 2020 20:04:24
User entered '23 Sep 2020 16:04'	System	23 Sep 2020 20:04:24

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:24:58
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 14:21:32

FDA-CBER-2022-1614-2919114

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:24:58
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 14:21:32

FDA-CBER-2022-1614-2919115

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
Data entry locked.	System	18 Sep 2020 14:21:32
User entered 'Day 7'	System	18 Sep 2020 14:21:32

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:24:58
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-24T13:39:40', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '65503c49-5eb4-48b8-a726-1aa31883fd6b'	System	24 Sep 2020 17:39:59
User entered 'Does not interfere with activity (2)'	System	24 Sep 2020 17:39:59

FDA-CBER-2022-1614-2919117

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:24:58
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-24T13:39:43', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '65503c49-5eb4-48b8-a726-1aa31883fd6b'	System	24 Sep 2020 17:39:59
User entered 'No (N)'	System	24 Sep 2020 17:39:59

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:24:58
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-24T13:39:51', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '65503c49-5eb4-48b8-a726-1aa31883fd6b'	System	24 Sep 2020 17:39:59
User entered 'No (N)'	System	24 Sep 2020 17:39:59

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:24:58
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-24T13:39:54', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '65503c49-5eb4-48b8-a726-1aa31883fd6b'	System	24 Sep 2020 17:39:59
User entered 'None (1)'	System	24 Sep 2020 17:39:59

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:24:58
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-24T13:39:57', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '65503c49-5eb4-48b8-a726-1aa31883fd6b'	System	24 Sep 2020 17:39:59
User entered '24 Sep 2020 13:39'	System	24 Sep 2020 17:39:59

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:24:58
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 14:21:32

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:24:58
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 14:21:32

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
Data entry locked.	System	18 Sep 2020 14:21:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 14:21:32

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:24:58
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-18T10:49:15', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'f50ae205-84d4-46b8-9a46-156aaae0ed30'	System	18 Sep 2020 14:49:38
User entered 'None (0)'	System	18 Sep 2020 14:49:38

FDA-CBER-2022-1614-2919125

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:24:58
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-18T10:49:18', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'f50ae205-84d4-46b8-9a46-156aaae0ed30'	System	18 Sep 2020 14:49:38
User entered 'None (0)'	System	18 Sep 2020 14:49:38

FDA-CBER-2022-1614-2919126

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:24:58
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-18T10:49:20', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'f50ae205-84d4-46b8-9a46-156aaae0ed30'	System	18 Sep 2020 14:49:38
User entered 'None (0)'	System	18 Sep 2020 14:49:38

FDA-CBER-2022-1614-2919127

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:24:58
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-18T10:49:22', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'f50ae205-84d4-46b8-9a46-156aaae0ed30'	System	18 Sep 2020 14:49:38
User entered 'None (0)'	System	18 Sep 2020 14:49:38

FDA-CBER-2022-1614-2919128

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:24:58
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-18T10:49:25', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'f50ae205-84d4-46b8-9a46-156aaae0ed30'	System	18 Sep 2020 14:49:38
User entered 'None (0)'	System	18 Sep 2020 14:49:38

FDA-CBER-2022-1614-2919129

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:24:58
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-18T10:49:27', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'f50ae205-84d4-46b8-9a46-156aaae0ed30'	System	18 Sep 2020 14:49:38
User entered 'None (0)'	System	18 Sep 2020 14:49:38

FDA-CBER-2022-1614-2919130

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:24:58
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-18T10:49:32', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'f50ae205-84d4-46b8-9a46-156aaae0ed30'	System	18 Sep 2020 14:49:38
User entered 'No (N)'	System	18 Sep 2020 14:49:38

FDA-CBER-2022-1614-2919131

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:24:58
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-18T10:49:36', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'f50ae205-84d4-46b8-9a46-156aaae0ed30'	System	18 Sep 2020 14:49:38
User entered '18 Sep 2020 10:49'	System	18 Sep 2020 14:49:38

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:24:58
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '18 Sep 2020 10:37'	System	18 Sep 2020 14:21:32

FDA-CBER-2022-1614-2919133

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:24:58
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '18 Sep 2020 13:07'	System	18 Sep 2020 14:21:32

FDA-CBER-2022-1614-2919134

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
Data entry locked.	System	18 Sep 2020 14:21:32
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 14:21:32

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:24:58
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-18T17:10:29', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'c5941405-592a-4a2c-92a4-d75ed41b5dea'	System	18 Sep 2020 21:11:10
User entered 'None (0)'	System	18 Sep 2020 21:11:10

FDA-CBER-2022-1614-2919136

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:24:58
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-18T17:10:34', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'c5941405-592a-4a2c-92a4-d75ed41b5dea'	System	18 Sep 2020 21:11:10
User entered 'None (0)'	System	18 Sep 2020 21:11:10

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:24:58
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-18T17:10:37', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'c5941405-592a-4a2c-92a4-d75ed41b5dea'	System	18 Sep 2020 21:11:10
User entered 'None (0)'	System	18 Sep 2020 21:11:10

FDA-CBER-2022-1614-2919138

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:24:58
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-18T17:10:42', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'c5941405-592a-4a2c-92a4-d75ed41b5dea'	System	18 Sep 2020 21:11:10
User entered 'None (0)'	System	18 Sep 2020 21:11:10

FDA-CBER-2022-1614-2919139

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:24:58
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-18T17:10:45', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'c5941405-592a-4a2c-92a4-d75ed41b5dea'	System	18 Sep 2020 21:11:10
User entered 'None (0)'	System	18 Sep 2020 21:11:10

FDA-CBER-2022-1614-2919140

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:24:58
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-18T17:10:48', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'c5941405-592a-4a2c-92a4-d75ed41b5dea'	System	18 Sep 2020 21:11:10
User entered 'None (0)'	System	18 Sep 2020 21:11:10

FDA-CBER-2022-1614-2919141

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:24:58
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-18T17:11:02', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'c5941405-592a-4a2c-92a4-d75ed41b5dea'	System	18 Sep 2020 21:11:10
User entered 'No (N)'	System	18 Sep 2020 21:11:10

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:24:58
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-18T17:11:06', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'c5941405-592a-4a2c-92a4-d75ed41b5dea'	System	18 Sep 2020 21:11:10
User entered '18 Sep 2020 17:11'	System	18 Sep 2020 21:11:10

FDA-CBER-2022-1614-2919143

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:24:58
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '18 Sep 2020 14:02'	System	18 Sep 2020 14:21:32

FDA-CBER-2022-1614-2919144

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:24:58
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 14:21:32

FDA-CBER-2022-1614-2919145

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
Data entry locked.	System	18 Sep 2020 14:21:32
User entered 'Day 2'	System	18 Sep 2020 14:21:32

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:24:58
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-19T17:04:53', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'a9504fde-e8d5-4a7e-8ec9-4874ac4a0a3c'	System	19 Sep 2020 21:05:21
User entered 'None (0)'	System	19 Sep 2020 21:05:21

FDA-CBER-2022-1614-2919147

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:24:58
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-19T17:04:57', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'a9504fde-e8d5-4a7e-8ec9-4874ac4a0a3c'	System	19 Sep 2020 21:05:21
User entered 'No interference with activity (1)'	System	19 Sep 2020 21:05:21

FDA-CBER-2022-1614-2919148

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:24:58
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-19T17:05:02', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'a9504fde-e8d5-4a7e-8ec9-4874ac4a0a3c'	System	19 Sep 2020 21:05:21
User entered 'None (0)'	System	19 Sep 2020 21:05:21

FDA-CBER-2022-1614-2919149

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:24:58
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-19T17:05:06', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'a9504fde-e8d5-4a7e-8ec9-4874ac4a0a3c'	System	19 Sep 2020 21:05:21
User entered 'None (0)'	System	19 Sep 2020 21:05:21

FDA-CBER-2022-1614-2919150

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:24:58
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-19T17:05:09', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'a9504fde-e8d5-4a7e-8ec9-4874ac4a0a3c'	System	19 Sep 2020 21:05:21
User entered 'None (0)'	System	19 Sep 2020 21:05:21

FDA-CBER-2022-1614-2919151

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:24:58
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-19T17:05:12', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'a9504fde-e8d5-4a7e-8ec9-4874ac4a0a3c'	System	19 Sep 2020 21:05:21
User entered 'None (0)'	System	19 Sep 2020 21:05:21

FDA-CBER-2022-1614-2919152

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:24:58
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-19T17:05:15', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'a9504fde-e8d5-4a7e-8ec9-4874ac4a0a3c'	System	19 Sep 2020 21:05:21
User entered 'No (N)'	System	19 Sep 2020 21:05:21

FDA-CBER-2022-1614-2919153

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:24:58
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-19T17:05:19', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'a9504fde-e8d5-4a7e-8ec9-4874ac4a0a3c'	System	19 Sep 2020 21:05:21
User entered '19 Sep 2020 17:05'	System	19 Sep 2020 21:05:21

FDA-CBER-2022-1614-2919154

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:24:58
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 14:21:32

FDA-CBER-2022-1614-2919155

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:24:58
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 14:21:32

FDA-CBER-2022-1614-2919156

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
Data entry locked.	System	18 Sep 2020 14:21:32
User entered 'Day 3'	System	18 Sep 2020 14:21:32

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:24:58
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-20T12:25:13', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'c676e7eb-8079-435c-a892-fb10559d2773'	System	20 Sep 2020 16:26:04
User entered 'None (0)'	System	20 Sep 2020 16:26:04

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:24:58
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-20T12:25:20', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'c676e7eb-8079-435c-a892-fb10559d2773'	System	20 Sep 2020 16:26:04
User entered 'None (0)'	System	20 Sep 2020 16:26:04

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:24:58
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-20T12:25:24', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'c676e7eb-8079-435c-a892-fb10559d2773'	System	20 Sep 2020 16:26:04
User entered 'None (0)'	System	20 Sep 2020 16:26:04

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:24:58
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-20T12:25:28', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'c676e7eb-8079-435c-a892-fb10559d2773'	System	20 Sep 2020 16:26:04
User entered 'None (0)'	System	20 Sep 2020 16:26:04

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:24:58
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-20T12:25:31', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'c676e7eb-8079-435c-a892-fb10559d2773'	System	20 Sep 2020 16:26:04
User entered 'None (0)'	System	20 Sep 2020 16:26:04

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:24:58
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-20T12:25:39', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'c676e7eb-8079-435c-a892-fb10559d2773'	System	20 Sep 2020 16:26:04
User entered 'None (0)'	System	20 Sep 2020 16:26:04

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:24:58
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-20T12:25:53', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'c676e7eb-8079-435c-a892-fb10559d2773'	System	20 Sep 2020 16:26:04
User entered 'No (N)'	System	20 Sep 2020 16:26:04

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:24:58
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-20T12:26:01', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'c676e7eb-8079-435c-a892-fb10559d2773'	System	20 Sep 2020 16:26:04
User entered '20 Sep 2020 12:26'	System	20 Sep 2020 16:26:04

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:24:58
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 14:21:32

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:24:58
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 14:21:32

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
Data entry locked.	System	18 Sep 2020 14:21:32
User entered 'Day 4'	System	18 Sep 2020 14:21:32

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:24:58
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-21T17:30:40', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '658f0c8e-59f3-40dc-a5c9-1723c960b20f'	System	21 Sep 2020 21:31:10
User entered 'None (0)'	System	21 Sep 2020 21:31:10

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:24:58
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-21T17:30:43', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '658f0c8e-59f3-40dc-a5c9-1723c960b20f'	System	21 Sep 2020 21:31:10
User entered 'None (0)'	System	21 Sep 2020 21:31:10

FDA-CBER-2022-1614-2919170

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:24:58
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-21T17:30:47', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '658f0c8e-59f3-40dc-a5c9-1723c960b20f'	System	21 Sep 2020 21:31:10
User entered 'None (0)'	System	21 Sep 2020 21:31:10

FDA-CBER-2022-1614-2919171

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:24:58
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-21T17:30:50', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '658f0c8e-59f3-40dc-a5c9-1723c960b20f'	System	21 Sep 2020 21:31:10
User entered 'None (0)'	System	21 Sep 2020 21:31:10

FDA-CBER-2022-1614-2919172

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:24:58
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-21T17:30:53', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '658f0c8e-59f3-40dc-a5c9-1723c960b20f'	System	21 Sep 2020 21:31:10
User entered 'None (0)'	System	21 Sep 2020 21:31:10

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:24:58
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-21T17:30:55', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '658f0c8e-59f3-40dc-a5c9-1723c960b20f'	System	21 Sep 2020 21:31:10
User entered 'None (0)'	System	21 Sep 2020 21:31:10

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:24:58
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-21T17:31:01', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '658f0c8e-59f3-40dc-a5c9-1723c960b20f'	System	21 Sep 2020 21:31:10
User entered 'No (N)'	System	21 Sep 2020 21:31:10

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:24:58
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-21T17:31:04', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '658f0c8e-59f3-40dc-a5c9-1723c960b20f'	System	21 Sep 2020 21:31:10
User entered '21 Sep 2020 17:31'	System	21 Sep 2020 21:31:10

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:24:58
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 14:21:32

FDA-CBER-2022-1614-2919177

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:24:58
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 14:21:32

FDA-CBER-2022-1614-2919178

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
Data entry locked.	System	18 Sep 2020 14:21:32
User entered 'Day 5'	System	18 Sep 2020 14:21:32

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:24:58
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-22T23:13:27', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'c03157a7-f747-4dc7-9a81-990d1e15cdc4'	System	23 Sep 2020 03:13:49
User entered 'None (0)'	System	23 Sep 2020 03:13:49

FDA-CBER-2022-1614-2919180

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:24:58
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-22T23:13:30', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'c03157a7-f747-4dc7-9a81-990d1e15cdc4'	System	23 Sep 2020 03:13:49
User entered 'None (0)'	System	23 Sep 2020 03:13:49

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:24:58
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-22T23:13:32', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'c03157a7-f747-4dc7-9a81-990d1e15cdc4'	System	23 Sep 2020 03:13:49
User entered 'None (0)'	System	23 Sep 2020 03:13:49

FDA-CBER-2022-1614-2919182

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:24:58
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-22T23:13:35', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'c03157a7-f747-4dc7-9a81-990d1e15cdc4'	System	23 Sep 2020 03:13:49
User entered 'None (0)'	System	23 Sep 2020 03:13:49

FDA-CBER-2022-1614-2919183

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:24:58
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-22T23:13:38', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'c03157a7-f747-4dc7-9a81-990d1e15cdc4'	System	23 Sep 2020 03:13:49
User entered 'None (0)'	System	23 Sep 2020 03:13:49

FDA-CBER-2022-1614-2919184

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:24:58
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-22T23:13:41', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'c03157a7-f747-4dc7-9a81-990d1e15cdc4'	System	23 Sep 2020 03:13:49
User entered 'None (0)'	System	23 Sep 2020 03:13:49

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:24:58
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-22T23:13:45', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'c03157a7-f747-4dc7-9a81-990d1e15cdc4'	System	23 Sep 2020 03:13:49
User entered 'No (N)'	System	23 Sep 2020 03:13:49

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:24:58
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-22T23:13:48', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'c03157a7-f747-4dc7-9a81-990d1e15cdc4'	System	23 Sep 2020 03:13:49
User entered '22 Sep 2020 23:13'	System	23 Sep 2020 03:13:49

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:24:58
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 14:21:32

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:24:58
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 14:21:32

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
Data entry locked.	System	18 Sep 2020 14:21:32
User entered 'Day 6'	System	18 Sep 2020 14:21:32

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:24:58
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-23T16:04:26', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'c848e1e7-15e1-4770-afd0-47b6cdfad538'	System	23 Sep 2020 20:05:03
User entered 'None (0)'	System	23 Sep 2020 20:05:03

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:24:58
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-23T16:04:32', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'c848e1e7-15e1-4770-afd0-47b6cdfad538'	System	23 Sep 2020 20:05:03
User entered 'No interference with activity (1)'	System	23 Sep 2020 20:05:03

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:24:58
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-23T16:04:36', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'c848e1e7-15e1-4770-afd0-47b6cdfad538'	System	23 Sep 2020 20:05:03
User entered 'None (0)'	System	23 Sep 2020 20:05:03

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:24:58
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-23T16:04:41', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'c848e1e7-15e1-4770-afd0-47b6cdfad538'	System	23 Sep 2020 20:05:03
User entered 'None (0)'	System	23 Sep 2020 20:05:03

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:24:58
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-23T16:04:46', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'c848e1e7-15e1-4770-afd0-47b6cdfad538'	System	23 Sep 2020 20:05:03
User entered 'None (0)'	System	23 Sep 2020 20:05:03

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:24:58
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-23T16:04:49', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'c848e1e7-15e1-4770-afd0-47b6cdfad538'	System	23 Sep 2020 20:05:03
User entered 'None (0)'	System	23 Sep 2020 20:05:03

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:24:58
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-23T16:04:52', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'c848e1e7-15e1-4770-afd0-47b6cdfad538'	System	23 Sep 2020 20:05:03
User entered 'No (N)'	System	23 Sep 2020 20:05:03

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:24:58
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-23T16:04:58', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'c848e1e7-15e1-4770-afd0-47b6cdfad538'	System	23 Sep 2020 20:05:03
User entered '23 Sep 2020 16:04'	System	23 Sep 2020 20:05:03

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:24:58
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 14:21:32

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:24:58
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 14:21:32

FDA-CBER-2022-1614-2919200

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
Data entry locked.	System	18 Sep 2020 14:21:32
User entered 'Day 7'	System	18 Sep 2020 14:21:32

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:24:58
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-24T13:40:07', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'c21b1ac0-b59c-4752-98ee-aaa7bb4d43ff'	System	24 Sep 2020 17:40:37
User entered 'None (0)'	System	24 Sep 2020 17:40:37

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:24:58
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-24T13:40:10', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'c21b1ac0-b59c-4752-98ee-aaa7bb4d43ff'	System	24 Sep 2020 17:40:37
User entered 'None (0)'	System	24 Sep 2020 17:40:37

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:24:58
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-24T13:40:15', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'c21b1ac0-b59c-4752-98ee-aaa7bb4d43ff'	System	24 Sep 2020 17:40:37
User entered 'None (0)'	System	24 Sep 2020 17:40:37

FDA-CBER-2022-1614-2919204

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:24:58
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-24T13:40:19', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'c21b1ac0-b59c-4752-98ee-aaa7bb4d43ff'	System	24 Sep 2020 17:40:37
User entered 'None (0)'	System	24 Sep 2020 17:40:37

FDA-CBER-2022-1614-2919205

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:24:58
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-24T13:40:21', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'c21b1ac0-b59c-4752-98ee-aaa7bb4d43ff'	System	24 Sep 2020 17:40:37
User entered 'None (0)'	System	24 Sep 2020 17:40:37

FDA-CBER-2022-1614-2919206

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:24:58
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-24T13:40:24', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'c21b1ac0-b59c-4752-98ee-aaa7bb4d43ff'	System	24 Sep 2020 17:40:37
User entered 'None (0)'	System	24 Sep 2020 17:40:37

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:24:58
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-24T13:40:27', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'c21b1ac0-b59c-4752-98ee-aaa7bb4d43ff'	System	24 Sep 2020 17:40:37
User entered 'No (N)'	System	24 Sep 2020 17:40:37

FDA-CBER-2022-1614-2919208

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:24:58
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-24T13:40:30', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'c21b1ac0-b59c-4752-98ee-aaa7bb4d43ff'	System	24 Sep 2020 17:40:37
User entered '24 Sep 2020 13:40'	System	24 Sep 2020 17:40:37

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:24:58
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 14:21:32

US3662116
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:24:58
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 14:21:32

FDA-CBER-2022-1614-2919211

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Pain_Day(8)
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
Data entry locked.	System	24 Sep 2020 17:39:59
User entered 'Day 8'	System	24 Sep 2020 17:39:59

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Pain_Day(8)
Generated On: 10 Jun 2021 09:24:58
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-25T12:18:57', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '5b79f45a-e986-4e56-8a9e-f732a49ad46c'	System	25 Sep 2020 16:19:01
User entered 'None (1)'	System	25 Sep 2020 16:19:01

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Pain_Day(8)
Generated On: 10 Jun 2021 09:24:58
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-25T12:19:00', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '5b79f45a-e986-4e56-8a9e-f732a49ad46c'	System	25 Sep 2020 16:19:01
User entered '25 Sep 2020 12:19'	System	25 Sep 2020 16:19:01

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Pain_Day(8)
Generated On: 10 Jun 2021 09:24:58
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 17:39:59

FDA-CBER-2022-1614-2919215

US3662116
Folder: Diary Dose 1 (1)
Form: Injection Pain_Day(8)
Generated On: 10 Jun 2021 09:24:58
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 17:39:59

FDA-CBER-2022-1614-2919216

US3662116
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
Data entry locked.	System	23 Sep 2020 20:05:03
User entered 'Day 8'	System	23 Sep 2020 20:05:03

US3662116
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 10 Jun 2021 09:24:58
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-25T12:19:06', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'becdebd9-042a-41ea-ad9f-659fba215cba'	System	25 Sep 2020 16:19:10
User entered 'No (N)'	System	25 Sep 2020 16:19:10

US3662116
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 10 Jun 2021 09:24:58
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-09-25T12:19:09', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'becdebd9-042a-41ea-ad9f-659fba215cba'	System	25 Sep 2020 16:19:10
User entered '25 Sep 2020 12:19'	System	25 Sep 2020 16:19:10

US3662116
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 10 Jun 2021 09:24:58
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 20:05:03

FDA-CBER-2022-1614-2919220

US3662116
Folder: Diary Dose 1 (1)
Form: Medical Attention_Day(8)
Generated On: 10 Jun 2021 09:24:58
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 20:05:03

FDA-CBER-2022-1614-2919221

US3662116
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:58
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:59:10
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	25 Sep 2020 15:28:08

US3662116
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:58
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:59:10
User entered '25 Sep 2020'	Brenda Miller (b) (4) (b) (4)	25 Sep 2020 15:28:08

US3662116
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:58
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:59:10
User entered 'Contact Made (CONTACT MADE)'	Brenda Miller (b) (4) (b) (4)	25 Sep 2020 15:28:08

US3662116
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:58
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:59:10
User entered empty.	Brenda Miller (b) (4) (b) (4)	25 Sep 2020 15:28:08

US3662116
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:24:58
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:45:43
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	05 Oct 2020 13:23:35

US3662116
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:24:58
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User entered '1'	System	05 Oct 2020 13:23:35

FDA-CBER-2022-1614-2919227

US3662116
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:58
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:46:08
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	05 Oct 2020 13:23:51

US3662116
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:58
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:46:08
User entered '02 Oct 2020'	Brenda Miller (b) (4) (b) (4)	05 Oct 2020 13:23:51

US3662116
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:58
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:46:08
User entered 'Contact Made (CONTACT MADE)'	Brenda Miller (b) (4) (b) (4)	05 Oct 2020 13:23:51

US3662116
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:58
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:46:08
User entered empty.	Brenda Miller (b) (4) (b) (4)	05 Oct 2020 13:23:51

US3662116
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:24:58
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:46:17
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 19:16:47

US3662116
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:24:58
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User entered '1'	System	09 Oct 2020 19:16:47

FDA-CBER-2022-1614-2919233

US3662116
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:58
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:46:30
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 19:17:08

US3662116
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:58
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:46:30
User entered '09 Oct 2020'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 19:17:08

US3662116
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:58
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:46:30
User entered 'Contact Made (CONTACT MADE)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 19:17:08

US3662116
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:58
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:46:30
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 19:17:08

US3662116
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:24:58
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:46:34
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	09 Oct 2020 19:17:15

US3662116
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:24:58
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User entered '1'	System	09 Oct 2020 19:17:15

US3662116
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:24:58
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:47:06
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	21 Oct 2020 14:43:29

US3662116
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:24:58
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:47:06
User entered '16 Oct 2020'	Brenda Miller (b) (4) (b) (4)	21 Oct 2020 14:43:29

US3662116
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:24:58
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:47:06
User entered 'Clinic (Clinic)'	Brenda Miller (b) (4) (b) (4)	21 Oct 2020 14:43:29

US3662116
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:24:58
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User entered 'VISIT2'	System	21 Oct 2020 14:43:29

FDA-CBER-2022-1614-2919243

US3662116
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:24:58
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User accepted default value 'Pre-Dose (PREDOSE)'	Brenda Miller (b) (4) (b) (4)	21 Oct 2020 14:45:05

FDA-CBER-2022-1614-2919244

US3662116
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:24:58
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:47:32
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	21 Oct 2020 14:45:05

US3662116
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:24:58
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:47:32
User entered '16 Oct 2020'	Brenda Miller (b) (4) (b) (4)	21 Oct 2020 14:45:05

US3662116
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:24:58
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:47:32
User entered '09:43'	Brenda Miller (b) (4) (b) (4)	21 Oct 2020 14:45:05

US3662116
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:24:58
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User entered '16 Oct 2020 09:43'	System	21 Oct 2020 14:45:05

US3662116
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:24:58
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:47:32
User entered '97.6' F	Brenda Miller (b) (4) (b) (4)	21 Oct 2020 14:45:05

US3662116
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:24:58
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:47:32
User entered 'Other (Other)'	Brenda Miller (b) (4) (b) (4)	21 Oct 2020 14:45:05

US3662116
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:24:58
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:47:32
User entered 'INFRARED THERMOMETER'	Brenda Miller (b) (4) (b) (4)	21 Oct 2020 14:45:05

US3662116
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:24:58
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:47:32
User entered '96'	Brenda Miller (b) (4) (b) (4)	21 Oct 2020 14:45:05

US3662116
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:24:58
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User entered 'bpm'	System	21 Oct 2020 14:45:05

FDA-CBER-2022-1614-2919253

US3662116
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:24:58
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:47:32
User entered '16'	Brenda Miller (b) (4) (b) (4)	21 Oct 2020 14:45:05

US3662116
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:24:58
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User entered 'breaths/min'	System	21 Oct 2020 14:45:05

US3662116
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:24:58
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:47:32
User entered '122'	Brenda Miller (b) (4) (b) (4)	21 Oct 2020 14:45:05

US3662116
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:24:58
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User entered 'mmHg'	System	21 Oct 2020 14:45:05

FDA-CBER-2022-1614-2919257

US3662116
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:24:58
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:47:32
User entered '87'	Brenda Miller (b) (4) (b) (4)	21 Oct 2020 14:45:05

US3662116
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:24:58
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User entered 'mmHg'	System	21 Oct 2020 14:45:05

US3662116
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:24:58
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User accepted default value 'Post-Dose (POSTDOSE)'	Brenda Miller (b) (4) (b) (4)	21 Oct 2020 14:45:05

FDA-CBER-2022-1614-2919260

US3662116
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:24:58
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:47:32
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	21 Oct 2020 14:45:05

US3662116
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:24:58
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:47:32
User entered '16 Oct 2020'	Brenda Miller (b) (4) (b) (4)	21 Oct 2020 14:45:05

US3662116
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:24:58
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:47:32
User entered '11:05'	Brenda Miller (b) (4) (b) (4)	21 Oct 2020 14:45:05

US3662116
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:24:58
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User entered '16 Oct 2020 11:05'	System	21 Oct 2020 14:45:05

FDA-CBER-2022-1614-2919264

US3662116
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:24:58
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:47:32
User entered '97.3' F	Brenda Miller (b) (4) (b) (4)	21 Oct 2020 14:45:05

US3662116
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:24:58
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:47:32
User entered 'Other (Other)'	Brenda Miller (b) (4) (b) (4)	21 Oct 2020 14:45:05

US3662116
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:24:58
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:47:32
User entered 'INFRARED THERMOMETER'	Brenda Miller (b) (4) (b) (4)	21 Oct 2020 14:45:05

US3662116
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:24:58
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:47:32
User entered '94'	Brenda Miller (b) (4) (b) (4)	21 Oct 2020 14:45:05

US3662116
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:24:58
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User entered 'bpm'	System	21 Oct 2020 14:45:05

FDA-CBER-2022-1614-2919269

US3662116
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:24:58
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:47:32
User entered '16'	Brenda Miller (b) (4) (b) (4)	21 Oct 2020 14:45:05

US3662116
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:24:58
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User entered 'breaths/min'	System	21 Oct 2020 14:45:05

US3662116
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:24:58
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:47:32
User entered '113'	Brenda Miller (b) (4) (b) (4)	21 Oct 2020 14:45:05

US3662116
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:24:58
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User entered 'mmHg'	System	21 Oct 2020 14:45:05

US3662116
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:24:58
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:47:32
User entered '89'	Brenda Miller (b) (4) (b) (4)	21 Oct 2020 14:45:05

US3662116
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:24:58
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User entered 'mmHg'	System	21 Oct 2020 14:45:05

FDA-CBER-2022-1614-2919275

US3662116
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:24:58
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:48:58
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	21 Oct 2020 14:45:22

US3662116
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:24:58
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:48:58
User entered '16 Oct 2020'	Brenda Miller (b) (4) (b) (4)	21 Oct 2020 14:45:22

US3662116
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:24:58
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:49:14
User entered 'Yes (Y)'	michelle saemann (b) (4) (b) (4)	16 Oct 2020 14:39:37

US3662116
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:24:58
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:49:14
User entered empty.	michelle saemann (b) (4) (b) (4)	16 Oct 2020 14:39:37

US3662116
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:24:58
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)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:49:14
User entered empty.	michelle saemann (b) (4) (b) (4)	16 Oct 2020 14:39:37

US3662116
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:24:58
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User entered 'MRNA-1273 OR PLACEBO'	System	16 Oct 2020 14:39:37

US3662116
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:24:58
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:49:14
User entered '16 Oct 2020'	michelle saemann (b) (4) (b) (4)	16 Oct 2020 14:39:37

US3662116
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:24:58
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:49:14
User entered '10:35'	michelle saemann (b) (4) (b) (4)	16 Oct 2020 14:39:37

US3662116
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:24:58
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User entered '16 Oct 2020 10:35'	System	16 Oct 2020 14:39:37

US3662116
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:24:58
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:49:14
User entered 'Left Arm (LEFT ARM)'	michelle saemann (b) (4) (b) (4)	16 Oct 2020 14:39:37

US3662116
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:24:58
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:49:14
User entered 'ONCE'	System	16 Oct 2020 14:39:37

US3662116
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:24:58
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User entered 'INTRAMUSCULAR'	System	16 Oct 2020 14:39:37

US3662116
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:24:58
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:49:30
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	21 Oct 2020 14:46:05

US3662116
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:24:58
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:49:30
User entered '16 Oct 2020'	Brenda Miller (b) (4) (b) (4)	21 Oct 2020 14:46:05

US3662116
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:24:58
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:49:30
User entered '09:55'	Brenda Miller (b) (4) (b) (4)	21 Oct 2020 14:46:05

US3662116
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:24:58
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User entered '16 Oct 2020 09:55'	System	21 Oct 2020 14:46:05

US3662116
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 10 Jun 2021 09:24:58
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:49:45
User entered '16 Oct 2020'	Brenda Miller (b) (4) (b) (4)	21 Oct 2020 14:46:22

US3662116
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:24:58
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Brenda Miller (b) (4) (b) (4)	21 Oct 2020 14:46:22

US3662116
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:24:58
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:49:45
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	21 Oct 2020 14:46:22

US3662116
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:24:58
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:49:45
User entered '09:50'	Brenda Miller (b) (4) (b) (4)	21 Oct 2020 14:46:22

US3662116
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:24:58
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User entered '16 Oct 2020 09:50'	System	21 Oct 2020 14:46:22

US3662116
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:24:58
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Brenda Miller (b) (4) (b) (4)	21 Oct 2020 14:46:22

US3662116
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:24:58
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:49:45
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	21 Oct 2020 14:46:22

US3662116
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:24:58
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:49:45
User entered empty.	Brenda Miller (b) (4) (b) (4)	21 Oct 2020 14:46:22

US3662116
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:24:58
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User entered empty.	System	21 Oct 2020 14:46:22

US3662116
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:24:58
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:49:51
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	21 Oct 2020 14:46:28

US3662116
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:24:58
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User entered '1'	System	21 Oct 2020 14:46:28

FDA-CBER-2022-1614-2919302

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
Data entry locked.	System	16 Oct 2020 14:39:37
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Oct 2020 14:39:37

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:24:58
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-16T11:07:07', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '2dde1c5e-8cc5-494d-a6a6-c5685a577d37'	System	16 Oct 2020 15:07:26
User entered 'Yes (Y)'	System	16 Oct 2020 15:07:26

FDA-CBER-2022-1614-2919304

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:24:58
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-16T11:07:15', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '2dde1c5e-8cc5-494d-a6a6-c5685a577d37'	System	16 Oct 2020 15:07:26
User entered '97.3'	System	16 Oct 2020 15:07:26

FDA-CBER-2022-1614-2919305

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:24:58
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-16T11:07:19', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '2dde1c5e-8cc5-494d-a6a6-c5685a577d37'	System	16 Oct 2020 15:07:26
User entered 'No (N)'	System	16 Oct 2020 15:07:26

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:24:58
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-16T11:07:23', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '2dde1c5e-8cc5-494d-a6a6-c5685a577d37'	System	16 Oct 2020 15:07:26
User entered '16 Oct 2020 11:07'	System	16 Oct 2020 15:07:26

FDA-CBER-2022-1614-2919307

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:24:58
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '16 Oct 2020 10:55'	System	16 Oct 2020 14:39:37

FDA-CBER-2022-1614-2919308

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:24:58
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '16 Oct 2020 13:25'	System	16 Oct 2020 14:39:37

FDA-CBER-2022-1614-2919309

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
Data entry locked.	System	16 Oct 2020 14:39:37
User entered 'Day 1, after vaccination (at home)'	System	16 Oct 2020 14:39:37

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:24:58
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-16T17:16:22', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'cbdbd284-5695-4aaa-a025-b7b84c21c799'	System	16 Oct 2020 21:16:40
User entered 'Yes (Y)'	System	16 Oct 2020 21:16:40

FDA-CBER-2022-1614-2919311

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:24:58
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-16T17:16:28', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'cbdbd284-5695-4aaa-a025-b7b84c21c799'	System	16 Oct 2020 21:16:40
User entered '97.9'	System	16 Oct 2020 21:16:40

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:24:58
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-16T17:16:33', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'cbdbd284-5695-4aaa-a025-b7b84c21c799'	System	16 Oct 2020 21:16:40
User entered 'No (N)'	System	16 Oct 2020 21:16:40

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:24:58
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-16T17:16:36', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'cbdbd284-5695-4aaa-a025-b7b84c21c799'	System	16 Oct 2020 21:16:40
User entered '16 Oct 2020 17:16'	System	16 Oct 2020 21:16:40

FDA-CBER-2022-1614-2919314

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:24:58
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '16 Oct 2020 14:20'	System	16 Oct 2020 14:39:37

FDA-CBER-2022-1614-2919315

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:24:58
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '17 Oct 2020 11:59'	System	16 Oct 2020 14:39:37

FDA-CBER-2022-1614-2919316

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
Data entry locked.	System	16 Oct 2020 14:39:37
User entered 'Day 2'	System	16 Oct 2020 14:39:37

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:24:58
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-17T13:07:15', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '9127c226-1890-4ffe-bd42-18b5cdc10e6d'	System	17 Oct 2020 17:07:44
User entered 'Yes (Y)'	System	17 Oct 2020 17:07:44

FDA-CBER-2022-1614-2919318

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:24:58
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-17T13:07:23', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '9127c226-1890-4ffe-bd42-18b5cdc10e6d'	System	17 Oct 2020 17:07:44
User entered '99.2'	System	17 Oct 2020 17:07:44

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:24:58
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-17T13:07:28', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '9127c226-1890-4ffe-bd42-18b5cdc10e6d'	System	17 Oct 2020 17:07:44
User entered 'Yes (Y)'	System	17 Oct 2020 17:07:44

FDA-CBER-2022-1614-2919320

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:24:58
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
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)	28 Oct 2020 10:34:51
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 'Participant contacted and medication added to concomitant medication page' (Site from System).	Brenda Miller (b) (4) (b) (4)	26 Oct 2020 13:35:30
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	17 Oct 2020 17:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-17T13:07:38', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '9127c226-1890-4ffe-bd42-18b5cdc10e6d'	System	17 Oct 2020 17:07:44
User entered '1'	System	17 Oct 2020 17:07:44

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:24:58
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-17T13:07:38', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '9127c226-1890-4ffe-bd42-18b5cdc10e6d'	System	17 Oct 2020 17:07:44
User entered '0'	System	17 Oct 2020 17:07:44

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:24:58
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-17T13:07:41', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '9127c226-1890-4ffe-bd42-18b5cdc10e6d'	System	17 Oct 2020 17:07:44
User entered '17 Oct 2020 13:07'	System	17 Oct 2020 17:07:44

FDA-CBER-2022-1614-2919323

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:24:58
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '17 Oct 2020 12:00'	System	16 Oct 2020 14:39:37

FDA-CBER-2022-1614-2919324

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:24:58
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '18 Oct 2020 11:59'	System	16 Oct 2020 14:39:37

FDA-CBER-2022-1614-2919325

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
Data entry locked.	System	16 Oct 2020 14:39:37
User entered 'Day 3'	System	16 Oct 2020 14:39:37

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:24:58
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-18T15:32:05', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'a4d42ab8-07a9-4dee-af1e-71043f5d7b26'	System	18 Oct 2020 19:32:29
User entered 'Yes (Y)'	System	18 Oct 2020 19:32:29

FDA-CBER-2022-1614-2919327

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:24:58
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-18T15:32:14', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'a4d42ab8-07a9-4dee-af1e-71043f5d7b26'	System	18 Oct 2020 19:32:29
User entered '99.1'	System	18 Oct 2020 19:32:29

FDA-CBER-2022-1614-2919328

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:24:58
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-18T15:32:24', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'a4d42ab8-07a9-4dee-af1e-71043f5d7b26'	System	18 Oct 2020 19:32:29
User entered 'No (N)'	System	18 Oct 2020 19:32:29

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:24:58
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-18T15:32:27', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'a4d42ab8-07a9-4dee-af1e-71043f5d7b26'	System	18 Oct 2020 19:32:29
User entered '18 Oct 2020 15:32'	System	18 Oct 2020 19:32:29

FDA-CBER-2022-1614-2919330

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:24:58
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '18 Oct 2020 12:00'	System	16 Oct 2020 14:39:37

FDA-CBER-2022-1614-2919331

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:24:58
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '19 Oct 2020 11:59'	System	16 Oct 2020 14:39:37

FDA-CBER-2022-1614-2919332

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
Data entry locked.	System	16 Oct 2020 14:39:37
User entered 'Day 4'	System	16 Oct 2020 14:39:37

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:24:58
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-19T18:37:04', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'ffb51b3a-15c7-40f4-8a8a-7606e4afcebb'	System	19 Oct 2020 22:37:20
User entered 'Yes (Y)'	System	19 Oct 2020 22:37:20

FDA-CBER-2022-1614-2919334

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:24:58
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-19T18:37:10', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'ffb51b3a-15c7-40f4-8a8a-7606e4afcebb'	System	19 Oct 2020 22:37:20
User entered '99.1'	System	19 Oct 2020 22:37:20

FDA-CBER-2022-1614-2919335

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:24:58
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-19T18:37:14', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'ffb51b3a-15c7-40f4-8a8a-7606e4afcebb'	System	19 Oct 2020 22:37:20
User entered 'No (N)'	System	19 Oct 2020 22:37:20

FDA-CBER-2022-1614-2919336

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:24:58
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-19T18:37:18', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'ffb51b3a-15c7-40f4-8a8a-7606e4afcebb'	System	19 Oct 2020 22:37:20
User entered '19 Oct 2020 18:37'	System	19 Oct 2020 22:37:20

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:24:58
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '19 Oct 2020 12:00'	System	16 Oct 2020 14:39:37

FDA-CBER-2022-1614-2919338

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:24:58
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '20 Oct 2020 11:59'	System	16 Oct 2020 14:39:37

FDA-CBER-2022-1614-2919339

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
Data entry locked.	System	16 Oct 2020 14:39:37
User entered 'Day 5'	System	16 Oct 2020 14:39:37

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:24:58
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-20T15:10:43', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '92df61ca-c66c-46a4-be31-371cfa419d96'	System	20 Oct 2020 19:11:02
User entered 'Yes (Y)'	System	20 Oct 2020 19:11:02

FDA-CBER-2022-1614-2919341

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:24:58
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-20T15:10:49', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '92df61ca-c66c-46a4-be31-371cfa419d96'	System	20 Oct 2020 19:11:02
User entered '97.6'	System	20 Oct 2020 19:11:02

FDA-CBER-2022-1614-2919342

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:24:58
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-20T15:10:53', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '92df61ca-c66c-46a4-be31-371cfa419d96'	System	20 Oct 2020 19:11:02
User entered 'No (N)'	System	20 Oct 2020 19:11:02

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:24:58
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-20T15:10:56', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '92df61ca-c66c-46a4-be31-371cfa419d96'	System	20 Oct 2020 19:11:02
User entered '20 Oct 2020 15:10'	System	20 Oct 2020 19:11:02

FDA-CBER-2022-1614-2919344

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:24:58
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '20 Oct 2020 12:00'	System	16 Oct 2020 14:39:37

FDA-CBER-2022-1614-2919345

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:24:58
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '21 Oct 2020 11:59'	System	16 Oct 2020 14:39:37

FDA-CBER-2022-1614-2919346

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
Data entry locked.	System	16 Oct 2020 14:39:37
User entered 'Day 6'	System	16 Oct 2020 14:39:37

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:24:58
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-21T14:32:43', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'bdd30ee1-d7f6-4463-a01e-6ba9d08edc96'	System	21 Oct 2020 18:33:04
User entered 'Yes (Y)'	System	21 Oct 2020 18:33:04

FDA-CBER-2022-1614-2919348

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:24:58
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-21T14:32:49', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'bdd30ee1-d7f6-4463-a01e-6ba9d08edc96'	System	21 Oct 2020 18:33:04
User entered '98.7'	System	21 Oct 2020 18:33:04

FDA-CBER-2022-1614-2919349

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:24:58
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-21T14:32:53', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'bdd30ee1-d7f6-4463-a01e-6ba9d08edc96'	System	21 Oct 2020 18:33:04
User entered 'No (N)'	System	21 Oct 2020 18:33:04

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:24:58
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-21T14:32:56', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'bdd30ee1-d7f6-4463-a01e-6ba9d08edc96'	System	21 Oct 2020 18:33:04
User entered '21 Oct 2020 14:32'	System	21 Oct 2020 18:33:04

FDA-CBER-2022-1614-2919351

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:24:58
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '21 Oct 2020 12:00'	System	16 Oct 2020 14:39:37

FDA-CBER-2022-1614-2919352

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:24:58
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '22 Oct 2020 11:59'	System	16 Oct 2020 14:39:37

FDA-CBER-2022-1614-2919353

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
Data entry locked.	System	16 Oct 2020 14:39:37
User entered 'Day 7'	System	16 Oct 2020 14:39:37

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:24:58
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-22T12:09:10', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '38c1c1c9-ffec-436a-8558-cc26ce965719'	System	22 Oct 2020 16:09:25
User entered 'Yes (Y)'	System	22 Oct 2020 16:09:25

FDA-CBER-2022-1614-2919355

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:24:58
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-22T12:09:15', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '38c1c1c9-ffec-436a-8558-cc26ce965719'	System	22 Oct 2020 16:09:25
User entered '98.2'	System	22 Oct 2020 16:09:25

FDA-CBER-2022-1614-2919356

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:24:58
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-22T12:09:19', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '38c1c1c9-ffec-436a-8558-cc26ce965719'	System	22 Oct 2020 16:09:25
User entered 'No (N)'	System	22 Oct 2020 16:09:25

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:24:58
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-22T12:09:22', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '38c1c1c9-ffec-436a-8558-cc26ce965719'	System	22 Oct 2020 16:09:25
User entered '22 Oct 2020 12:09'	System	22 Oct 2020 16:09:25

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:24:58
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '22 Oct 2020 12:00'	System	16 Oct 2020 14:39:37

FDA-CBER-2022-1614-2919359

US3662116
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:24:58
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '23 Oct 2020 11:59'	System	16 Oct 2020 14:39:37

FDA-CBER-2022-1614-2919360

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
Data entry locked.	System	16 Oct 2020 14:39:37
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Oct 2020 14:39:37

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:24:58
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-16T11:07:31', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '2ce51f3f-8d8b-4ce9-85f8-133e5e643443'	System	16 Oct 2020 15:08:03
User entered 'None (1)'	System	16 Oct 2020 15:08:03

FDA-CBER-2022-1614-2919362

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:24:58
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-16T11:07:34', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '2ce51f3f-8d8b-4ce9-85f8-133e5e643443'	System	16 Oct 2020 15:08:03
User entered 'No (N)'	System	16 Oct 2020 15:08:03

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:24:58
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-16T11:07:37', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '2ce51f3f-8d8b-4ce9-85f8-133e5e643443'	System	16 Oct 2020 15:08:03
User entered 'No (N)'	System	16 Oct 2020 15:08:03

FDA-CBER-2022-1614-2919364

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:24:58
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-16T11:07:40', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '2ce51f3f-8d8b-4ce9-85f8-133e5e643443'	System	16 Oct 2020 15:08:03
User entered 'None (1)'	System	16 Oct 2020 15:08:03

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:24:58
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-16T11:07:42', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '2ce51f3f-8d8b-4ce9-85f8-133e5e643443'	System	16 Oct 2020 15:08:03
User entered '16 Oct 2020 11:07'	System	16 Oct 2020 15:08:03

FDA-CBER-2022-1614-2919366

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:24:58
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '16 Oct 2020 10:55'	System	16 Oct 2020 14:39:37

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:24:58
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '16 Oct 2020 13:25'	System	16 Oct 2020 14:39:37

FDA-CBER-2022-1614-2919368

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
Data entry locked.	System	16 Oct 2020 14:39:37
User entered 'Day 1, after vaccination (at home)'	System	16 Oct 2020 14:39:37

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:24:58
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-16T17:16:48', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '34396e81-29cc-4b7f-9b59-7bd16f2ccdbe'	System	16 Oct 2020 21:17:05
User entered 'Does not interfere with activity (2)'	System	16 Oct 2020 21:17:05

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:24:58
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-16T17:16:51', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '34396e81-29cc-4b7f-9b59-7bd16f2ccdbe'	System	16 Oct 2020 21:17:05
User entered 'No (N)'	System	16 Oct 2020 21:17:05

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:24:58
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-16T17:16:54', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '34396e81-29cc-4b7f-9b59-7bd16f2ccdbe'	System	16 Oct 2020 21:17:05
User entered 'No (N)'	System	16 Oct 2020 21:17:05

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:24:58
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-16T17:16:58', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '34396e81-29cc-4b7f-9b59-7bd16f2ccdbe'	System	16 Oct 2020 21:17:05
User entered 'None (1)'	System	16 Oct 2020 21:17:05

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:24:58
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-16T17:17:01', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '34396e81-29cc-4b7f-9b59-7bd16f2ccdbe'	System	16 Oct 2020 21:17:05
User entered '16 Oct 2020 17:17'	System	16 Oct 2020 21:17:05

FDA-CBER-2022-1614-2919374

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:24:58
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '16 Oct 2020 14:20'	System	16 Oct 2020 14:39:37

FDA-CBER-2022-1614-2919375

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:24:58
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '17 Oct 2020 11:59'	System	16 Oct 2020 14:39:37

FDA-CBER-2022-1614-2919376

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
Data entry locked.	System	16 Oct 2020 14:39:37
User entered 'Day 2'	System	16 Oct 2020 14:39:37

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:24:58
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-17T13:08:00', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '3e2d4a21-e58a-4408-8d8c-0e31d24fb007'	System	17 Oct 2020 17:08:18
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	17 Oct 2020 17:08:18

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:24:58
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-17T13:08:04', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '3e2d4a21-e58a-4408-8d8c-0e31d24fb007'	System	17 Oct 2020 17:08:18
User entered 'No (N)'	System	17 Oct 2020 17:08:18

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:24:58
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-17T13:08:07', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '3e2d4a21-e58a-4408-8d8c-0e31d24fb007'	System	17 Oct 2020 17:08:18
User entered 'No (N)'	System	17 Oct 2020 17:08:18

FDA-CBER-2022-1614-2919380

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:24:58
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-17T13:08:12', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '3e2d4a21-e58a-4408-8d8c-0e31d24fb007'	System	17 Oct 2020 17:08:18
User entered 'None (1)'	System	17 Oct 2020 17:08:18

FDA-CBER-2022-1614-2919381

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:24:58
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-17T13:08:15', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '3e2d4a21-e58a-4408-8d8c-0e31d24fb007'	System	17 Oct 2020 17:08:18
User entered '17 Oct 2020 13:08'	System	17 Oct 2020 17:08:18

FDA-CBER-2022-1614-2919382

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:24:58
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '17 Oct 2020 12:00'	System	16 Oct 2020 14:39:37

FDA-CBER-2022-1614-2919383

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:24:58
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '18 Oct 2020 11:59'	System	16 Oct 2020 14:39:37

FDA-CBER-2022-1614-2919384

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
Data entry locked.	System	16 Oct 2020 14:39:37
User entered 'Day 3'	System	16 Oct 2020 14:39:37

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:24:58
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-18T15:32:34', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'f7d58d3a-92dd-4e95-888b-b9c561ef62c2'	System	18 Oct 2020 19:32:48
User entered 'Does not interfere with activity (2)'	System	18 Oct 2020 19:32:48

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:24:58
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-18T15:32:37', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'f7d58d3a-92dd-4e95-888b-b9c561ef62c2'	System	18 Oct 2020 19:32:48
User entered 'No (N)'	System	18 Oct 2020 19:32:48

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:24:58
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-18T15:32:40', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'f7d58d3a-92dd-4e95-888b-b9c561ef62c2'	System	18 Oct 2020 19:32:48
User entered 'No (N)'	System	18 Oct 2020 19:32:48

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:24:58
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-18T15:32:44', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'f7d58d3a-92dd-4e95-888b-b9c561ef62c2'	System	18 Oct 2020 19:32:48
User entered 'None (1)'	System	18 Oct 2020 19:32:48

FDA-CBER-2022-1614-2919389

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:24:58
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-18T15:32:47', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'f7d58d3a-92dd-4e95-888b-b9c561ef62c2'	System	18 Oct 2020 19:32:48
User entered '18 Oct 2020 15:32'	System	18 Oct 2020 19:32:48

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:24:58
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '18 Oct 2020 12:00'	System	16 Oct 2020 14:39:37

FDA-CBER-2022-1614-2919391

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:24:58
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '19 Oct 2020 11:59'	System	16 Oct 2020 14:39:37

FDA-CBER-2022-1614-2919392

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
Data entry locked.	System	16 Oct 2020 14:39:37
User entered 'Day 4'	System	16 Oct 2020 14:39:37

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:24:58
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-19T18:37:27', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '7af013ea-1f12-4ccd-b0d9-94dddf7daa86'	System	19 Oct 2020 22:37:40
User entered 'Does not interfere with activity (2)'	System	19 Oct 2020 22:37:40

FDA-CBER-2022-1614-2919394

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:24:58
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-19T18:37:30', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '7af013ea-1f12-4ccd-b0d9-94dddf7daa86'	System	19 Oct 2020 22:37:40
User entered 'No (N)'	System	19 Oct 2020 22:37:40

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:24:58
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-19T18:37:32', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '7af013ea-1f12-4ccd-b0d9-94dddf7daa86'	System	19 Oct 2020 22:37:40
User entered 'No (N)'	System	19 Oct 2020 22:37:40

FDA-CBER-2022-1614-2919396

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:24:58
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-19T18:37:37', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '7af013ea-1f12-4ccd-b0d9-94dddf7daa86'	System	19 Oct 2020 22:37:40
User entered 'None (1)'	System	19 Oct 2020 22:37:40

FDA-CBER-2022-1614-2919397

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:24:58
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-19T18:37:39', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '7af013ea-1f12-4ccd-b0d9-94dddf7daa86'	System	19 Oct 2020 22:37:40
User entered '19 Oct 2020 18:37'	System	19 Oct 2020 22:37:40

FDA-CBER-2022-1614-2919398

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:24:58
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '19 Oct 2020 12:00'	System	16 Oct 2020 14:39:37

FDA-CBER-2022-1614-2919399

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:24:58
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '20 Oct 2020 11:59'	System	16 Oct 2020 14:39:37

FDA-CBER-2022-1614-2919400

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
Data entry locked.	System	16 Oct 2020 14:39:37
User entered 'Day 5'	System	16 Oct 2020 14:39:37

FDA-CBER-2022-1614-2919401

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:24:58
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-20T15:11:14', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '6e300733-fb4b-4c38-904e-70e23bdcac5d'	System	20 Oct 2020 19:11:33
User entered 'None (1)'	System	20 Oct 2020 19:11:33

FDA-CBER-2022-1614-2919402

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:24:58
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-20T15:11:19', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '6e300733-fb4b-4c38-904e-70e23bdcac5d'	System	20 Oct 2020 19:11:33
User entered 'No (N)'	System	20 Oct 2020 19:11:33

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:24:58
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-20T15:11:22', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '6e300733-fb4b-4c38-904e-70e23bdcac5d'	System	20 Oct 2020 19:11:33
User entered 'No (N)'	System	20 Oct 2020 19:11:33

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:24:58
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-20T15:11:25', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '6e300733-fb4b-4c38-904e-70e23bdcac5d'	System	20 Oct 2020 19:11:33
User entered 'None (1)'	System	20 Oct 2020 19:11:33

FDA-CBER-2022-1614-2919405

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:24:58
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-20T15:11:28', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '6e300733-fb4b-4c38-904e-70e23bdcac5d'	System	20 Oct 2020 19:11:33
User entered '20 Oct 2020 15:11'	System	20 Oct 2020 19:11:33

FDA-CBER-2022-1614-2919406

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:24:58
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '20 Oct 2020 12:00'	System	16 Oct 2020 14:39:37

FDA-CBER-2022-1614-2919407

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:24:58
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '21 Oct 2020 11:59'	System	16 Oct 2020 14:39:37

FDA-CBER-2022-1614-2919408

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
Data entry locked.	System	16 Oct 2020 14:39:37
User entered 'Day 6'	System	16 Oct 2020 14:39:37

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:24:58
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-21T14:33:02', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'e5c1b42f-92fa-4fca-92e6-15bb04a872af'	System	21 Oct 2020 18:33:21
User entered 'None (1)'	System	21 Oct 2020 18:33:21

FDA-CBER-2022-1614-2919410

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:24:58
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-21T14:33:05', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'e5c1b42f-92fa-4fca-92e6-15bb04a872af'	System	21 Oct 2020 18:33:21
User entered 'No (N)'	System	21 Oct 2020 18:33:21

FDA-CBER-2022-1614-2919411

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:24:58
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-21T14:33:08', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'e5c1b42f-92fa-4fca-92e6-15bb04a872af'	System	21 Oct 2020 18:33:21
User entered 'No (N)'	System	21 Oct 2020 18:33:21

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:24:58
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-21T14:33:11', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'e5c1b42f-92fa-4fca-92e6-15bb04a872af'	System	21 Oct 2020 18:33:21
User entered 'None (1)'	System	21 Oct 2020 18:33:21

FDA-CBER-2022-1614-2919413

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:24:58
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-21T14:33:16', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'e5c1b42f-92fa-4fca-92e6-15bb04a872af'	System	21 Oct 2020 18:33:21
User entered '21 Oct 2020 14:33'	System	21 Oct 2020 18:33:21

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:24:58
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '21 Oct 2020 12:00'	System	16 Oct 2020 14:39:37

FDA-CBER-2022-1614-2919415

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:24:58
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '22 Oct 2020 11:59'	System	16 Oct 2020 14:39:37

FDA-CBER-2022-1614-2919416

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
Data entry locked.	System	16 Oct 2020 14:39:37
User entered 'Day 7'	System	16 Oct 2020 14:39:37

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:24:58
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-22T12:09:28', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'b9528684-8e91-4407-8309-448b680e3510'	System	22 Oct 2020 16:10:03
User entered 'None (1)'	System	22 Oct 2020 16:10:03

FDA-CBER-2022-1614-2919418

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:24:58
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-22T12:09:31', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'b9528684-8e91-4407-8309-448b680e3510'	System	22 Oct 2020 16:10:03
User entered 'No (N)'	System	22 Oct 2020 16:10:03

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:24:58
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-22T12:09:36', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'b9528684-8e91-4407-8309-448b680e3510'	System	22 Oct 2020 16:10:03
User entered 'No (N)'	System	22 Oct 2020 16:10:03

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:24:58
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-22T12:09:40', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'b9528684-8e91-4407-8309-448b680e3510'	System	22 Oct 2020 16:10:03
User entered 'None (1)'	System	22 Oct 2020 16:10:03

FDA-CBER-2022-1614-2919421

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:24:58
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-22T12:09:46', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'b9528684-8e91-4407-8309-448b680e3510'	System	22 Oct 2020 16:10:03
User entered '22 Oct 2020 12:09'	System	22 Oct 2020 16:10:03

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:24:58
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '22 Oct 2020 12:00'	System	16 Oct 2020 14:39:37

FDA-CBER-2022-1614-2919423

US3662116
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:24:58
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '23 Oct 2020 11:59'	System	16 Oct 2020 14:39:37

FDA-CBER-2022-1614-2919424

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
Data entry locked.	System	16 Oct 2020 14:39:37
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Oct 2020 14:39:37

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:24:58
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-16T11:07:48', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '1e678700-98b6-49fb-a128-e11012ccad0b'	System	16 Oct 2020 15:08:13
User entered 'None (0)'	System	16 Oct 2020 15:08:13

FDA-CBER-2022-1614-2919426

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:24:58
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-16T11:07:51', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '1e678700-98b6-49fb-a128-e11012ccad0b'	System	16 Oct 2020 15:08:13
User entered 'None (0)'	System	16 Oct 2020 15:08:13

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:24:58
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-16T11:07:53', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '1e678700-98b6-49fb-a128-e11012ccad0b'	System	16 Oct 2020 15:08:13
User entered 'None (0)'	System	16 Oct 2020 15:08:13

FDA-CBER-2022-1614-2919428

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:24:58
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-16T11:07:56', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '1e678700-98b6-49fb-a128-e11012ccad0b'	System	16 Oct 2020 15:08:13
User entered 'None (0)'	System	16 Oct 2020 15:08:13

FDA-CBER-2022-1614-2919429

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:24:58
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-16T11:07:59', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '1e678700-98b6-49fb-a128-e11012ccad0b'	System	16 Oct 2020 15:08:13
User entered 'None (0)'	System	16 Oct 2020 15:08:13

FDA-CBER-2022-1614-2919430

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:24:58
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-16T11:08:01', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '1e678700-98b6-49fb-a128-e11012ccad0b'	System	16 Oct 2020 15:08:13
User entered 'None (0)'	System	16 Oct 2020 15:08:13

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:24:58
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-16T11:08:07', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '1e678700-98b6-49fb-a128-e11012ccad0b'	System	16 Oct 2020 15:08:13
User entered 'No (N)'	System	16 Oct 2020 15:08:13

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:24:58
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-16T11:08:10', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '1e678700-98b6-49fb-a128-e11012ccad0b'	System	16 Oct 2020 15:08:13
User entered '16 Oct 2020 11:08'	System	16 Oct 2020 15:08:13

FDA-CBER-2022-1614-2919433

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:24:58
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '16 Oct 2020 10:55'	System	16 Oct 2020 14:39:37

FDA-CBER-2022-1614-2919434

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:24:58
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '16 Oct 2020 13:25'	System	16 Oct 2020 14:39:37

FDA-CBER-2022-1614-2919435

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
Data entry locked.	System	16 Oct 2020 14:39:37
User entered 'Day 1, after vaccination (at home)'	System	16 Oct 2020 14:39:37

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:24:58
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-16T17:17:07', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '6817606e-03bd-46ed-a7e8-46f6b850cfc5'	System	16 Oct 2020 21:17:31
User entered 'None (0)'	System	16 Oct 2020 21:17:31

FDA-CBER-2022-1614-2919437

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:24:58
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-16T17:17:11', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '6817606e-03bd-46ed-a7e8-46f6b850cfc5'	System	16 Oct 2020 21:17:31
User entered 'None (0)'	System	16 Oct 2020 21:17:31

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:24:58
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-16T17:17:14', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '6817606e-03bd-46ed-a7e8-46f6b850cfc5'	System	16 Oct 2020 21:17:31
User entered 'None (0)'	System	16 Oct 2020 21:17:31

FDA-CBER-2022-1614-2919439

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:24:58
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-16T17:17:17', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '6817606e-03bd-46ed-a7e8-46f6b850cfc5'	System	16 Oct 2020 21:17:31
User entered 'None (0)'	System	16 Oct 2020 21:17:31

FDA-CBER-2022-1614-2919440

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:24:58
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-16T17:17:19', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '6817606e-03bd-46ed-a7e8-46f6b850cfc5'	System	16 Oct 2020 21:17:31
User entered 'None (0)'	System	16 Oct 2020 21:17:31

FDA-CBER-2022-1614-2919441

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:24:58
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-16T17:17:21', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '6817606e-03bd-46ed-a7e8-46f6b850cfc5'	System	16 Oct 2020 21:17:31
User entered 'None (0)'	System	16 Oct 2020 21:17:31

FDA-CBER-2022-1614-2919442

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:24:58
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-16T17:17:24', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '6817606e-03bd-46ed-a7e8-46f6b850cfc5'	System	16 Oct 2020 21:17:31
User entered 'No (N)'	System	16 Oct 2020 21:17:31

FDA-CBER-2022-1614-2919443

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:24:58
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-16T17:17:27', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '6817606e-03bd-46ed-a7e8-46f6b850cfc5'	System	16 Oct 2020 21:17:31
User entered '16 Oct 2020 17:17'	System	16 Oct 2020 21:17:31

FDA-CBER-2022-1614-2919444

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:24:58
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '16 Oct 2020 14:20'	System	16 Oct 2020 14:39:37

FDA-CBER-2022-1614-2919445

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:24:58
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '17 Oct 2020 11:59'	System	16 Oct 2020 14:39:37

FDA-CBER-2022-1614-2919446

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
Data entry locked.	System	16 Oct 2020 14:39:37
User entered 'Day 2'	System	16 Oct 2020 14:39:37

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:24:58
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-17T13:08:27', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'a0c7f442-969d-4306-8e6e-dcc3e48f85ed'	System	17 Oct 2020 17:09:01
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	17 Oct 2020 17:09:01

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:24:58
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-17T13:08:31', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'a0c7f442-969d-4306-8e6e-dcc3e48f85ed'	System	17 Oct 2020 17:09:01
User entered 'No interference with activity (1)'	System	17 Oct 2020 17:09:01

FDA-CBER-2022-1614-2919449

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:24:58
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-17T13:08:35', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'a0c7f442-969d-4306-8e6e-dcc3e48f85ed'	System	17 Oct 2020 17:09:01
User entered 'No interference with activity (1)'	System	17 Oct 2020 17:09:01

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:24:58
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-17T13:08:42', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'a0c7f442-969d-4306-8e6e-dcc3e48f85ed'	System	17 Oct 2020 17:09:01
User entered 'None (0)'	System	17 Oct 2020 17:09:01

FDA-CBER-2022-1614-2919451

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:24:58
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-17T13:08:50', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'a0c7f442-969d-4306-8e6e-dcc3e48f85ed'	System	17 Oct 2020 17:09:01
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	17 Oct 2020 17:09:01

FDA-CBER-2022-1614-2919452

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:24:58
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-17T13:08:52', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'a0c7f442-969d-4306-8e6e-dcc3e48f85ed'	System	17 Oct 2020 17:09:01
User entered 'None (0)'	System	17 Oct 2020 17:09:01

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:24:58
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-17T13:08:56', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'a0c7f442-969d-4306-8e6e-dcc3e48f85ed'	System	17 Oct 2020 17:09:01
User entered 'No (N)'	System	17 Oct 2020 17:09:01

FDA-CBER-2022-1614-2919454

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:24:58
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-17T13:08:58', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'a0c7f442-969d-4306-8e6e-dcc3e48f85ed'	System	17 Oct 2020 17:09:01
User entered '17 Oct 2020 13:08'	System	17 Oct 2020 17:09:01

FDA-CBER-2022-1614-2919455

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:24:58
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '17 Oct 2020 12:00'	System	16 Oct 2020 14:39:37

FDA-CBER-2022-1614-2919456

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:24:58
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '18 Oct 2020 11:59'	System	16 Oct 2020 14:39:37

FDA-CBER-2022-1614-2919457

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
Data entry locked.	System	16 Oct 2020 14:39:37
User entered 'Day 3'	System	16 Oct 2020 14:39:37

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:24:58
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-18T15:32:55', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'cfce94bc-c69c-473d-9fa0-1147e43855ed'	System	18 Oct 2020 19:33:43
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	18 Oct 2020 19:33:43

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:24:58
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-18T15:33:00', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'cfce94bc-c69c-473d-9fa0-1147e43855ed'	System	18 Oct 2020 19:33:43
User entered 'Some interference with activity (2)'	System	18 Oct 2020 19:33:43

FDA-CBER-2022-1614-2919460

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:24:58
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-18T15:33:04', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'cfce94bc-c69c-473d-9fa0-1147e43855ed'	System	18 Oct 2020 19:33:43
User entered 'No interference with activity (1)'	System	18 Oct 2020 19:33:43

FDA-CBER-2022-1614-2919461

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:24:58
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-18T15:33:11', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'cfce94bc-c69c-473d-9fa0-1147e43855ed'	System	18 Oct 2020 19:33:43
User entered 'None (0)'	System	18 Oct 2020 19:33:43

FDA-CBER-2022-1614-2919462

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:24:58
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-18T15:33:20', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'cfce94bc-c69c-473d-9fa0-1147e43855ed'	System	18 Oct 2020 19:33:43
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	18 Oct 2020 19:33:43

FDA-CBER-2022-1614-2919463

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:24:58
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-18T15:33:24', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'cfce94bc-c69c-473d-9fa0-1147e43855ed'	System	18 Oct 2020 19:33:43
User entered 'No interference with activity (1)'	System	18 Oct 2020 19:33:43

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:24:58
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-18T15:33:27', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'cfce94bc-c69c-473d-9fa0-1147e43855ed'	System	18 Oct 2020 19:33:43
User entered 'No (N)'	System	18 Oct 2020 19:33:43

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:24:58
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-18T15:33:41', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'cfce94bc-c69c-473d-9fa0-1147e43855ed'	System	18 Oct 2020 19:33:43
User entered '18 Oct 2020 15:33'	System	18 Oct 2020 19:33:43

FDA-CBER-2022-1614-2919466

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:24:58
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '18 Oct 2020 12:00'	System	16 Oct 2020 14:39:37

FDA-CBER-2022-1614-2919467

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:24:58
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '19 Oct 2020 11:59'	System	16 Oct 2020 14:39:37

FDA-CBER-2022-1614-2919468

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
Data entry locked.	System	16 Oct 2020 14:39:37
User entered 'Day 4'	System	16 Oct 2020 14:39:37

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:24:58
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-19T18:37:46', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '86f61543-0da9-43a4-87d2-e0ace64d69d0'	System	19 Oct 2020 22:38:10
User entered 'None (0)'	System	19 Oct 2020 22:38:10

FDA-CBER-2022-1614-2919470

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:24:58
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-19T18:37:48', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '86f61543-0da9-43a4-87d2-e0ace64d69d0'	System	19 Oct 2020 22:38:10
User entered 'None (0)'	System	19 Oct 2020 22:38:10

FDA-CBER-2022-1614-2919471

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:24:58
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-19T18:37:55', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '86f61543-0da9-43a4-87d2-e0ace64d69d0'	System	19 Oct 2020 22:38:10
User entered 'None (0)'	System	19 Oct 2020 22:38:10

FDA-CBER-2022-1614-2919472

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:24:58
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-19T18:37:58', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '86f61543-0da9-43a4-87d2-e0ace64d69d0'	System	19 Oct 2020 22:38:10
User entered 'None (0)'	System	19 Oct 2020 22:38:10

FDA-CBER-2022-1614-2919473

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:24:58
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-19T18:38:01', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '86f61543-0da9-43a4-87d2-e0ace64d69d0'	System	19 Oct 2020 22:38:10
User entered 'None (0)'	System	19 Oct 2020 22:38:10

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:24:58
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-19T18:38:03', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '86f61543-0da9-43a4-87d2-e0ace64d69d0'	System	19 Oct 2020 22:38:10
User entered 'None (0)'	System	19 Oct 2020 22:38:10

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:24:58
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-19T18:38:06', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '86f61543-0da9-43a4-87d2-e0ace64d69d0'	System	19 Oct 2020 22:38:10
User entered 'No (N)'	System	19 Oct 2020 22:38:10

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:24:58
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-19T18:38:09', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '86f61543-0da9-43a4-87d2-e0ace64d69d0'	System	19 Oct 2020 22:38:10
User entered '19 Oct 2020 18:38'	System	19 Oct 2020 22:38:10

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:24:58
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '19 Oct 2020 12:00'	System	16 Oct 2020 14:39:37

FDA-CBER-2022-1614-2919478

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:24:58
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '20 Oct 2020 11:59'	System	16 Oct 2020 14:39:37

FDA-CBER-2022-1614-2919479

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
Data entry locked.	System	16 Oct 2020 14:39:37
User entered 'Day 5'	System	16 Oct 2020 14:39:37

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:24:58
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-20T15:11:34', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'df38674c-6c99-4766-9756-efd25eaf7bb6'	System	20 Oct 2020 19:12:00
User entered 'None (0)'	System	20 Oct 2020 19:12:00

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:24:58
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-20T15:11:37', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'df38674c-6c99-4766-9756-efd25eaf7bb6'	System	20 Oct 2020 19:12:00
User entered 'None (0)'	System	20 Oct 2020 19:12:00

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:24:58
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-20T15:11:40', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'df38674c-6c99-4766-9756-efd25eaf7bb6'	System	20 Oct 2020 19:12:00
User entered 'None (0)'	System	20 Oct 2020 19:12:00

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:24:58
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-20T15:11:44', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'df38674c-6c99-4766-9756-efd25eaf7bb6'	System	20 Oct 2020 19:12:00
User entered 'None (0)'	System	20 Oct 2020 19:12:00

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:24:58
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-20T15:11:46', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'df38674c-6c99-4766-9756-efd25eaf7bb6'	System	20 Oct 2020 19:12:00
User entered 'None (0)'	System	20 Oct 2020 19:12:00

FDA-CBER-2022-1614-2919485

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:24:58
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-20T15:11:49', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'df38674c-6c99-4766-9756-efd25eaf7bb6'	System	20 Oct 2020 19:12:00
User entered 'None (0)'	System	20 Oct 2020 19:12:00

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:24:58
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-20T15:11:52', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'df38674c-6c99-4766-9756-efd25eaf7bb6'	System	20 Oct 2020 19:12:00
User entered 'No (N)'	System	20 Oct 2020 19:12:00

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:24:58
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-20T15:11:55', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'df38674c-6c99-4766-9756-efd25eaf7bb6'	System	20 Oct 2020 19:12:00
User entered '20 Oct 2020 15:11'	System	20 Oct 2020 19:12:00

FDA-CBER-2022-1614-2919488

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:24:58
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '20 Oct 2020 12:00'	System	16 Oct 2020 14:39:37

FDA-CBER-2022-1614-2919489

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:24:58
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '21 Oct 2020 11:59'	System	16 Oct 2020 14:39:37

FDA-CBER-2022-1614-2919490

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
Data entry locked.	System	16 Oct 2020 14:39:37
User entered 'Day 6'	System	16 Oct 2020 14:39:37

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:24:58
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-21T14:33:23', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '00b0f502-b082-48ae-8c1d-180fd2ae8fd2'	System	21 Oct 2020 18:33:46
User entered 'None (0)'	System	21 Oct 2020 18:33:46

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:24:58
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-21T14:33:25', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '00b0f502-b082-48ae-8c1d-180fd2ae8fd2'	System	21 Oct 2020 18:33:46
User entered 'None (0)'	System	21 Oct 2020 18:33:46

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:24:58
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-21T14:33:28', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '00b0f502-b082-48ae-8c1d-180fd2ae8fd2'	System	21 Oct 2020 18:33:46
User entered 'None (0)'	System	21 Oct 2020 18:33:46

FDA-CBER-2022-1614-2919494

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:24:58
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-21T14:33:30', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '00b0f502-b082-48ae-8c1d-180fd2ae8fd2'	System	21 Oct 2020 18:33:46
User entered 'None (0)'	System	21 Oct 2020 18:33:46

FDA-CBER-2022-1614-2919495

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:24:58
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-21T14:33:32', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '00b0f502-b082-48ae-8c1d-180fd2ae8fd2'	System	21 Oct 2020 18:33:46
User entered 'None (0)'	System	21 Oct 2020 18:33:46

FDA-CBER-2022-1614-2919496

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:24:58
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-21T14:33:34', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '00b0f502-b082-48ae-8c1d-180fd2ae8fd2'	System	21 Oct 2020 18:33:46
User entered 'None (0)'	System	21 Oct 2020 18:33:46

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:24:58
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-21T14:33:39', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '00b0f502-b082-48ae-8c1d-180fd2ae8fd2'	System	21 Oct 2020 18:33:46
User entered 'No (N)'	System	21 Oct 2020 18:33:46

FDA-CBER-2022-1614-2919498

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:24:58
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-21T14:33:42', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '00b0f502-b082-48ae-8c1d-180fd2ae8fd2'	System	21 Oct 2020 18:33:46
User entered '21 Oct 2020 14:33'	System	21 Oct 2020 18:33:46

FDA-CBER-2022-1614-2919499

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:24:58
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '21 Oct 2020 12:00'	System	16 Oct 2020 14:39:37

FDA-CBER-2022-1614-2919500

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:24:58
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '22 Oct 2020 11:59'	System	16 Oct 2020 14:39:37

FDA-CBER-2022-1614-2919501

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
Data entry locked.	System	16 Oct 2020 14:39:37
User entered 'Day 7'	System	16 Oct 2020 14:39:37

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:24:58
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-22T12:09:55', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '3b4561c1-275e-46b9-9765-6ad166dca021'	System	22 Oct 2020 16:10:18
User entered 'None (0)'	System	22 Oct 2020 16:10:18

FDA-CBER-2022-1614-2919503

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:24:58
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-22T12:09:58', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '3b4561c1-275e-46b9-9765-6ad166dca021'	System	22 Oct 2020 16:10:18
User entered 'None (0)'	System	22 Oct 2020 16:10:18

FDA-CBER-2022-1614-2919504

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:24:58
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-22T12:10:00', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '3b4561c1-275e-46b9-9765-6ad166dca021'	System	22 Oct 2020 16:10:18
User entered 'None (0)'	System	22 Oct 2020 16:10:18

FDA-CBER-2022-1614-2919505

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:24:58
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-22T12:10:02', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '3b4561c1-275e-46b9-9765-6ad166dca021'	System	22 Oct 2020 16:10:18
User entered 'None (0)'	System	22 Oct 2020 16:10:18

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:24:58
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-22T12:10:05', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '3b4561c1-275e-46b9-9765-6ad166dca021'	System	22 Oct 2020 16:10:18
User entered 'None (0)'	System	22 Oct 2020 16:10:18

FDA-CBER-2022-1614-2919507

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:24:58
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-22T12:10:07', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '3b4561c1-275e-46b9-9765-6ad166dca021'	System	22 Oct 2020 16:10:18
User entered 'None (0)'	System	22 Oct 2020 16:10:18

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:24:58
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-22T12:10:11', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '3b4561c1-275e-46b9-9765-6ad166dca021'	System	22 Oct 2020 16:10:18
User entered 'No (N)'	System	22 Oct 2020 16:10:18

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:24:58
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-10-22T12:10:14', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '3b4561c1-275e-46b9-9765-6ad166dca021'	System	22 Oct 2020 16:10:18
User entered '22 Oct 2020 12:10'	System	22 Oct 2020 16:10:18

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:24:58
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '22 Oct 2020 12:00'	System	16 Oct 2020 14:39:37

FDA-CBER-2022-1614-2919511

US3662116
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:24:58
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
User entered '23 Oct 2020 11:59'	System	16 Oct 2020 14:39:37

FDA-CBER-2022-1614-2919512

US3662116
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:58
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:51:55
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	26 Oct 2020 13:36:56

US3662116
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:58
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:51:55
User entered '23 Oct 2020'	Brenda Miller (b) (4) (b) (4)	26 Oct 2020 13:36:56

US3662116
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:58
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:51:55
User entered 'Contact Made (CONTACT MADE)'	Brenda Miller (b) (4) (b) (4)	26 Oct 2020 13:36:56

US3662116
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:58
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:51:55
User entered empty.	Brenda Miller (b) (4) (b) (4)	26 Oct 2020 13:36:56

US3662116
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:24:58
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:51:58
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	26 Oct 2020 13:37:08

US3662116
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:24:58
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User entered '1'	System	26 Oct 2020 13:37:08

US3662116
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:58
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:52:21
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	03 Nov 2020 16:19:52

US3662116
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:58
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:52:21
User entered '30 Oct 2020'	Brenda Miller (b) (4) (b) (4)	03 Nov 2020 16:19:52

US3662116
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:58
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:52:21
User entered 'Contact Made (CONTACT MADE)'	Brenda Miller (b) (4) (b) (4)	03 Nov 2020 16:19:52

US3662116
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:58
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:52:21
User entered empty.	Brenda Miller (b) (4) (b) (4)	03 Nov 2020 16:19:52

US3662116
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:24:58
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:52:24
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	03 Nov 2020 16:20:03

US3662116
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:24:58
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User entered '1'	System	03 Nov 2020 16:20:03

US3662116
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:58
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:52:40
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	09 Nov 2020 20:25:55

US3662116
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:58
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:52:40
User entered '06 Nov 2020'	Brenda Miller (b) (4) (b) (4)	09 Nov 2020 20:25:55

US3662116
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:58
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:52:40
User entered 'Contact Made (CONTACT MADE)'	Brenda Miller (b) (4) (b) (4)	09 Nov 2020 20:25:55

US3662116
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:58
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:52:40
User entered empty.	Brenda Miller (b) (4) (b) (4)	09 Nov 2020 20:25:55

US3662116
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:24:58
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:52:48
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	09 Nov 2020 20:26:02

US3662116
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:24:58
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User entered '1'	System	09 Nov 2020 20:26:02

US3662116
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:24:58
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:02:04
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	16 Nov 2020 18:46:46

US3662116
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:24:58
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:02:04
User entered '16 Nov 2020'	Brenda Miller (b) (4) (b) (4)	16 Nov 2020 18:46:46

US3662116
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:24:58
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:02:04
User entered 'Clinic (Clinic)'	Brenda Miller (b) (4) (b) (4)	16 Nov 2020 18:46:46

US3662116
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:24:58
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User entered 'VISIT3'	System	16 Nov 2020 18:46:46

FDA-CBER-2022-1614-2919534

US3662116
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:58
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:02:49
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	16 Nov 2020 18:47:36

US3662116
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:58
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:02:49
User entered '16 Nov 2020'	Brenda Miller (b) (4) (b) (4)	16 Nov 2020 18:47:36

US3662116
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:58
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:02:49
User entered '11:15'	Brenda Miller (b) (4) (b) (4)	16 Nov 2020 18:47:36

US3662116
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:58
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User entered '16 Nov 2020 11:15'	System	16 Nov 2020 18:47:36

US3662116
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:58
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:02:49
User entered '97.7' F	Brenda Miller (b) (4) (b) (4)	16 Nov 2020 18:47:36

US3662116
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:58
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:02:49
User entered 'Other (Other)'	Brenda Miller (b) (4) (b) (4)	16 Nov 2020 18:47:36

US3662116
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:58
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:02:49
User entered 'INFRARED THERMOMETER'	Brenda Miller (b) (4)	16 Nov 2020 18:47:36

FDA-CBER-2022-1614-2919541

US3662116
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:58
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:02:49
User entered '87'	Brenda Miller (b) (4) (b) (4)	16 Nov 2020 18:47:36

US3662116
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:58
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User entered 'bpm'	System	16 Nov 2020 18:47:36

FDA-CBER-2022-1614-2919543

US3662116
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:58
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:02:49
User entered '18'	Brenda Miller (b) (4) (b) (4)	16 Nov 2020 18:47:36

US3662116
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:58
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User entered 'breaths/min'	System	16 Nov 2020 18:47:36

FDA-CBER-2022-1614-2919545

US3662116
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:58
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:02:49
User entered '112'	Brenda Miller (b) (4) (b) (4)	16 Nov 2020 18:47:36

US3662116
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:58
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User entered 'mmHg'	System	16 Nov 2020 18:47:36

FDA-CBER-2022-1614-2919547

US3662116
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:58
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:02:49
User entered '90'	Brenda Miller (b) (4) (b) (4)	16 Nov 2020 18:47:36

US3662116
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:58
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User entered 'mmHg'	System	16 Nov 2020 18:47:36

FDA-CBER-2022-1614-2919549

US3662116
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:58
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30

FDA-CBER-2022-1614-2919550

US3662116
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:58
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30

FDA-CBER-2022-1614-2919551

US3662116
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:24:58
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:02:55
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	16 Nov 2020 18:47:48

US3662116
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:24:58
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:02:55
User entered '16 Nov 2020'	Brenda Miller (b) (4) (b) (4)	16 Nov 2020 18:47:48

US3662116
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:24:58
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:02:59
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	16 Nov 2020 18:48:10

US3662116
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:24:58
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:02:59
User entered '16 Nov 2020'	Brenda Miller (b) (4) (b) (4)	16 Nov 2020 18:48:10

US3662116
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:24:58
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:02:59
User entered '11:40'	Brenda Miller (b) (4) (b) (4)	16 Nov 2020 18:48:10

US3662116
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:24:58
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User entered '16 Nov 2020 11:40'	System	16 Nov 2020 18:48:10

US3662116
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:24:58
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 16:03:03
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	16 Nov 2020 18:48:16

US3662116
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:24:58
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User entered '1'	System	16 Nov 2020 18:48:16

FDA-CBER-2022-1614-2919559

US3662116
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
Data entry locked.	System	18 Sep 2020 14:21:32
User entered 'Day 64'	System	18 Sep 2020 14:21:32

US3662116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:58

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-11-19T09:34:36', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '2198eae4-671d-4a32-bfa1-05ea8c5440c6'	System	19 Nov 2020 14:34:57
User entered 'No (N)'	System	19 Nov 2020 14:34:57

US3662116

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:58

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-11-19T09:34:43', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '2198eae4-671d-4a32-bfa1-05ea8c5440c6'	System	19 Nov 2020 14:34:57
User entered 'No (N)'	System	19 Nov 2020 14:34:57

US3662116
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-11-19T09:34:53', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '2198eae4-671d-4a32-bfa1-05ea8c5440c6'	System	19 Nov 2020 14:34:57
User entered '19 Nov 2020 09:34:53'	System	19 Nov 2020 14:34:57

US3662116
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
Data entry locked.	System	18 Sep 2020 14:21:32
User entered '18 Nov 2020 00:01'	System	18 Sep 2020 14:21:32

US3662116
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:46:44
Data entry locked.	System	18 Sep 2020 14:21:32
User entered '22 Nov 2020 23:59'	System	18 Sep 2020 14:21:32

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 09:27:37

US3662116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:58

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 (3143e46ca23a224e)', Time: '2020-11-22T07:48:26', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '6da9d474-58ed-4ad5-9fa5-e4366a7f4b21'	System	22 Nov 2020 12:48:37
User entered 'No (N)'	System	22 Nov 2020 12:48:37

US3662116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:58

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 (3143e46ca23a224e)', Time: '2020-11-22T07:48:32', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '6da9d474-58ed-4ad5-9fa5-e4366a7f4b21'	System	22 Nov 2020 12:48:37
User entered 'No (N)'	System	22 Nov 2020 12:48:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-11-22T07:48:35', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '6da9d474-58ed-4ad5-9fa5-e4366a7f4b21'	System	22 Nov 2020 12:48:37
User entered '22 Nov 2020 07:48:35'	System	22 Nov 2020 12:48:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 09:27:37

US3662116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:58

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 (3143e46ca23a224e)', Time: '2020-11-29T11:09:19', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '21b50c81-6c1c-4be3-a088-ba4109453e67'	System	29 Nov 2020 16:10:14
User entered 'Yes (Y)'	System	29 Nov 2020 16:10:14

US3662116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:58

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 (3143e46ca23a224e)', Time: '2020-11-29T11:09:32', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '21b50c81-6c1c-4be3-a088-ba4109453e67'	System	29 Nov 2020 16:10:14
User entered 'No (N)'	System	29 Nov 2020 16:10:14

US3662116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:58

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 (3143e46ca23a224e)', Time: '2020-11-29T11:09:50', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '21b50c81-6c1c-4be3-a088-ba4109453e67'	System	29 Nov 2020 16:10:14
User entered 'No (N)'	System	29 Nov 2020 16:10:14

US3662116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:58

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 (3143e46ca23a224e)', Time: '2020-11-29T11:10:03', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '21b50c81-6c1c-4be3-a088-ba4109453e67'	System	29 Nov 2020 16:10:14
User entered 'No (N)'	System	29 Nov 2020 16:10:14

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-11-29T11:10:10', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '21b50c81-6c1c-4be3-a088-ba4109453e67'	System	29 Nov 2020 16:10:14
User entered '29 Nov 2020 11:10:10'	System	29 Nov 2020 16:10:14

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 09:27:37

US3662116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:58

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 (3143e46ca23a224e)', Time: '2020-12-06T06:44:43', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'dd2cbe13-0cd0-4aa2-b56b-b6e893ce7b0a'	System	06 Dec 2020 11:44:54
User entered 'No (N)'	System	06 Dec 2020 11:44:54

US3662116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:58

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 (3143e46ca23a224e)', Time: '2020-12-06T06:44:47', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'dd2cbe13-0cd0-4aa2-b56b-b6e893ce7b0a'	System	06 Dec 2020 11:44:54
User entered 'No (N)'	System	06 Dec 2020 11:44:54

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-12-06T06:44:51', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'dd2cbe13-0cd0-4aa2-b56b-b6e893ce7b0a'	System	06 Dec 2020 11:44:54
User entered '06 Dec 2020 06:44:51'	System	06 Dec 2020 11:44:54

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 09:27:37

US3662116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:58

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 (3143e46ca23a224e)', Time: '2020-12-13T10:13:03', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '9fdbfcec-ba39-43bd-b5e3-94da5db198b6'	System	13 Dec 2020 15:13:13
User entered 'No (N)'	System	13 Dec 2020 15:13:13

US3662116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:58

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 (3143e46ca23a224e)', Time: '2020-12-13T10:13:06', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '9fdbfcec-ba39-43bd-b5e3-94da5db198b6'	System	13 Dec 2020 15:13:13
User entered 'No (N)'	System	13 Dec 2020 15:13:13

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-12-13T10:13:09', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '9fdbfcec-ba39-43bd-b5e3-94da5db198b6'	System	13 Dec 2020 15:13:13
User entered '13 Dec 2020 10:13:09'	System	13 Dec 2020 15:13:13

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 09:27:37

US3662116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:58

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 (3143e46ca23a224e)', Time: '2020-12-20T06:37:43', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '00f12705-5c64-4070-8065-d3c831bfd35a'	System	20 Dec 2020 11:37:53
User entered 'No (N)'	System	20 Dec 2020 11:37:53

US3662116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:58

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 (3143e46ca23a224e)', Time: '2020-12-20T06:37:46', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '00f12705-5c64-4070-8065-d3c831bfd35a'	System	20 Dec 2020 11:37:53
User entered 'No (N)'	System	20 Dec 2020 11:37:53

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-12-20T06:37:49', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '00f12705-5c64-4070-8065-d3c831bfd35a'	System	20 Dec 2020 11:37:53
User entered '20 Dec 2020 06:37:49'	System	20 Dec 2020 11:37:53

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 09:27:37

US3662116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:58

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 (3143e46ca23a224e)', Time: '2020-12-27T17:50:52', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'f265835f-da3f-4c0c-b385-31e8f3a7b74d'	System	27 Dec 2020 22:51:07
User entered 'No (N)'	System	27 Dec 2020 22:51:07

US3662116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:58

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 (3143e46ca23a224e)', Time: '2020-12-27T17:50:59', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'f265835f-da3f-4c0c-b385-31e8f3a7b74d'	System	27 Dec 2020 22:51:07
User entered 'No (N)'	System	27 Dec 2020 22:51:07

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2020-12-27T17:51:03', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'f265835f-da3f-4c0c-b385-31e8f3a7b74d'	System	27 Dec 2020 22:51:07
User entered '27 Dec 2020 17:51:03'	System	27 Dec 2020 22:51:07

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 09:27:37

US3662116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:58

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 (3143e46ca23a224e)', Time: '2021-01-03T07:35:14', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'caf3ea2a-909e-4606-a2aa-8de93e20b5e7'	System	03 Jan 2021 12:35:25
User entered 'No (N)'	System	03 Jan 2021 12:35:25

US3662116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:58

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 (3143e46ca23a224e)', Time: '2021-01-03T07:35:17', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'caf3ea2a-909e-4606-a2aa-8de93e20b5e7'	System	03 Jan 2021 12:35:25
User entered 'No (N)'	System	03 Jan 2021 12:35:25

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3143e46ca23a224e)', Time: '2021-01-03T07:35:20', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'caf3ea2a-909e-4606-a2aa-8de93e20b5e7'	System	03 Jan 2021 12:35:25
User entered '03 Jan 2021 07:35:20'	System	03 Jan 2021 12:35:25

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 09:27:37

US3662116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:58

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 (7f15e254a0935b5a)', Time: '2021-01-10T12:48:27', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'fa956866-1b7c-45e6-a556-75345e30da91'	System	10 Jan 2021 17:49:04
User entered 'No (N)'	System	10 Jan 2021 17:49:04

US3662116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:58

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 (7f15e254a0935b5a)', Time: '2021-01-10T12:48:46', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'fa956866-1b7c-45e6-a556-75345e30da91'	System	10 Jan 2021 17:49:04
User entered 'Yes (Y)'	System	10 Jan 2021 17:49:04

US3662116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:58

Please 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 (7f15e254a0935b5a)', Time: '2021-01-10T12:48:49', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'fa956866-1b7c-45e6-a556-75345e30da91'	System	10 Jan 2021 17:49:04
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	10 Jan 2021 17:49:04

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f15e254a0935b5a)', Time: '2021-01-10T12:48:53', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'fa956866-1b7c-45e6-a556-75345e30da91'	System	10 Jan 2021 17:49:04
User entered '10 Jan 2021 12:48:53'	System	10 Jan 2021 17:49:04

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 09:27:37

US3662116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:58

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 (7f15e254a0935b5a)', Time: '2021-01-17T21:23:16', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '9994d013-8293-4dfd-a77e-529a820a9e27'	System	18 Jan 2021 02:23:27
User entered 'No (N)'	System	18 Jan 2021 02:23:27

US3662116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:58

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 (7f15e254a0935b5a)', Time: '2021-01-17T21:23:19', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '9994d013-8293-4dfd-a77e-529a820a9e27'	System	18 Jan 2021 02:23:27
User entered 'No (N)'	System	18 Jan 2021 02:23:27

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f15e254a0935b5a)', Time: '2021-01-17T21:23:22', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '9994d013-8293-4dfd-a77e-529a820a9e27'	System	18 Jan 2021 02:23:27
User entered '17 Jan 2021 21:23:22'	System	18 Jan 2021 02:23:27

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 09:27:37

US3662116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:58

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 (7f15e254a0935b5a)', Time: '2021-01-26T20:06:04', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'e0ed819a-368e-4054-b09c-6206d083018e'	System	27 Jan 2021 01:30:36
User entered 'No (N)'	System	27 Jan 2021 01:30:36

US3662116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:58

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 (7f15e254a0935b5a)', Time: '2021-01-26T20:06:35', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'e0ed819a-368e-4054-b09c-6206d083018e'	System	27 Jan 2021 01:30:36
User entered 'No (N)'	System	27 Jan 2021 01:30:36

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f15e254a0935b5a)', Time: '2021-01-26T20:06:38', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'e0ed819a-368e-4054-b09c-6206d083018e'	System	27 Jan 2021 01:30:36
User entered '26 Jan 2021 20:06:38'	System	27 Jan 2021 01:30:36

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 09:27:37

US3662116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:58

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 (7f15e254a0935b5a)', Time: '2021-01-31T19:06:28', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'bcc10c8b-ae8d-477d-9ae0-cc47c0f4f893'	System	01 Feb 2021 00:07:14
User entered 'No (N)'	System	01 Feb 2021 00:07:14

US3662116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:58

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 (7f15e254a0935b5a)', Time: '2021-01-31T19:06:31', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'bcc10c8b-ae8d-477d-9ae0-cc47c0f4f893'	System	01 Feb 2021 00:07:14
User entered 'No (N)'	System	01 Feb 2021 00:07:14

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f15e254a0935b5a)', Time: '2021-01-31T19:06:36', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'bcc10c8b-ae8d-477d-9ae0-cc47c0f4f893'	System	01 Feb 2021 00:07:14
User entered '31 Jan 2021 19:06:36'	System	01 Feb 2021 00:07:14

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 09:27:37

US3662116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:58

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 (7f15e254a0935b5a)', Time: '2021-02-07T21:37:57', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '9ebd8c8a-4ded-4652-b0b8-ab1b6c26be4c'	System	08 Feb 2021 02:38:06
User entered 'No (N)'	System	08 Feb 2021 02:38:06

US3662116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:58

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 (7f15e254a0935b5a)', Time: '2021-02-07T21:38:00', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '9ebd8c8a-4ded-4652-b0b8-ab1b6c26be4c'	System	08 Feb 2021 02:38:06
User entered 'No (N)'	System	08 Feb 2021 02:38:06

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f15e254a0935b5a)', Time: '2021-02-07T21:38:03', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '9ebd8c8a-4ded-4652-b0b8-ab1b6c26be4c'	System	08 Feb 2021 02:38:06
User entered '07 Feb 2021 21:38:03'	System	08 Feb 2021 02:38:06

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 09:27:37

US3662116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:58

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 (7f15e254a0935b5a)', Time: '2021-02-15T11:35:18', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '64b4323e-b270-4df7-baec-3e56c9668254'	System	15 Feb 2021 16:36:07
User entered 'Yes (Y)'	System	15 Feb 2021 16:36:07

US3662116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:58

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 (7f15e254a0935b5a)', Time: '2021-02-15T11:35:25', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '64b4323e-b270-4df7-baec-3e56c9668254'	System	15 Feb 2021 16:36:07
User entered 'No (N)'	System	15 Feb 2021 16:36:07

US3662116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:58

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 (7f15e254a0935b5a)', Time: '2021-02-15T11:35:29', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '64b4323e-b270-4df7-baec-3e56c9668254'	System	15 Feb 2021 16:36:07
User entered 'No (N)'	System	15 Feb 2021 16:36:07

US3662116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:58

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 (7f15e254a0935b5a)', Time: '2021-02-15T11:35:43', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '64b4323e-b270-4df7-baec-3e56c9668254'	System	15 Feb 2021 16:36:07
User entered 'Yes (Y)'	System	15 Feb 2021 16:36:07

US3662116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:58

Please 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 (7f15e254a0935b5a)', Time: '2021-02-15T11:35:48', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '64b4323e-b270-4df7-baec-3e56c9668254'	System	15 Feb 2021 16:36:07
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	15 Feb 2021 16:36:07

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f15e254a0935b5a)', Time: '2021-02-15T11:35:56', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '64b4323e-b270-4df7-baec-3e56c9668254'	System	15 Feb 2021 16:36:07
User entered '15 Feb 2021 11:35:56'	System	15 Feb 2021 16:36:07

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 09:27:37

US3662116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:58

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 (7f15e254a0935b5a)', Time: '2021-02-21T13:34:36', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '006f4fb6-45fe-4b04-a461-2ad9f6eccec6'	System	21 Feb 2021 18:36:15
User entered 'Yes (Y)'	System	21 Feb 2021 18:36:15

US3662116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:58

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 (7f15e254a0935b5a)', Time: '2021-02-21T13:34:45', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '006f4fb6-45fe-4b04-a461-2ad9f6eccec6'	System	21 Feb 2021 18:36:15
User entered 'No (N)'	System	21 Feb 2021 18:36:15

US3662116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:58

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 (7f15e254a0935b5a)', Time: '2021-02-21T13:34:52', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '006f4fb6-45fe-4b04-a461-2ad9f6eccec6'	System	21 Feb 2021 18:36:15
User entered 'No (N)'	System	21 Feb 2021 18:36:15

US3662116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:58

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 (7f15e254a0935b5a)', Time: '2021-02-21T13:35:00', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '006f4fb6-45fe-4b04-a461-2ad9f6eccec6'	System	21 Feb 2021 18:36:15
User entered 'Yes (Y)'	System	21 Feb 2021 18:36:15

US3662116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:58

Please 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 (7f15e254a0935b5a)', Time: '2021-02-21T13:35:10', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '006f4fb6-45fe-4b04-a461-2ad9f6eccec6'	System	21 Feb 2021 18:36:15
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	21 Feb 2021 18:36:15

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f15e254a0935b5a)', Time: '2021-02-21T13:35:13', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '006f4fb6-45fe-4b04-a461-2ad9f6eccec6'	System	21 Feb 2021 18:36:15
User entered '21 Feb 2021 13:35:13'	System	21 Feb 2021 18:36:15

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 09:27:37

US3662116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:58

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 (7f15e254a0935b5a)', Time: '2021-03-01T06:24:45-05:00', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '78516e1a-0188-46bc-83d4-412377f71bc0'	System	01 Mar 2021 11:25:16
User entered 'No (N)'	System	01 Mar 2021 11:25:16

US3662116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:58

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 (7f15e254a0935b5a)', Time: '2021-03-01T06:24:59-05:00', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '78516e1a-0188-46bc-83d4-412377f71bc0'	System	01 Mar 2021 11:25:16
User entered 'Yes (Y)'	System	01 Mar 2021 11:25:16

US3662116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:58

Please 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 (7f15e254a0935b5a)', Time: '2021-03-01T06:25:03-05:00', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '78516e1a-0188-46bc-83d4-412377f71bc0'	System	01 Mar 2021 11:25:16
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	01 Mar 2021 11:25:16

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f15e254a0935b5a)', Time: '2021-03-01T06:25:06-05:00', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '78516e1a-0188-46bc-83d4-412377f71bc0'	System	01 Mar 2021 11:25:16
User entered '01 Mar 2021 06:25:06'	System	01 Mar 2021 11:25:16

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 09:27:37

US3662116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:58

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 (7f15e254a0935b5a)', Time: '2021-03-07T08:39:43-05:00', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '5181578f-ba74-463d-a2d6-f1066dd9bc74'	System	07 Mar 2021 13:39:54
User entered 'No (N)'	System	07 Mar 2021 13:39:54

US3662116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:58

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 (7f15e254a0935b5a)', Time: '2021-03-07T08:39:46-05:00', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '5181578f-ba74-463d-a2d6-f1066dd9bc74'	System	07 Mar 2021 13:39:54
User entered 'No (N)'	System	07 Mar 2021 13:39:54

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f15e254a0935b5a)', Time: '2021-03-07T08:39:49-05:00', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '5181578f-ba74-463d-a2d6-f1066dd9bc74'	System	07 Mar 2021 13:39:54
User entered '07 Mar 2021 08:39:49'	System	07 Mar 2021 13:39:54

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 09:27:37

US3662116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:58

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 (7f15e254a0935b5a)', Time: '2021-03-14T11:51:47-04:00', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '8bcaccd4-71c4-458e-8a40-354c1c24b9c8'	System	14 Mar 2021 15:52:06
User entered 'No (N)'	System	14 Mar 2021 15:52:06

US3662116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:58

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 (7f15e254a0935b5a)', Time: '2021-03-14T11:51:55-04:00', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '8bcaccd4-71c4-458e-8a40-354c1c24b9c8'	System	14 Mar 2021 15:52:06
User entered 'No (N)'	System	14 Mar 2021 15:52:06

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f15e254a0935b5a)', Time: '2021-03-14T11:52:01-04:00', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '8bcaccd4-71c4-458e-8a40-354c1c24b9c8'	System	14 Mar 2021 15:52:06
User entered '14 Mar 2021 11:52:01'	System	14 Mar 2021 15:52:06

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 09:27:37

US3662116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:58

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 (7f15e254a0935b5a)', Time: '2021-03-21T09:00:40-04:00', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'b09b3fb8-a1f2-4d13-9763-9155c8ea551d'	System	21 Mar 2021 13:00:48
User entered 'No (N)'	System	21 Mar 2021 13:00:48

US3662116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:58

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 (7f15e254a0935b5a)', Time: '2021-03-21T09:00:43-04:00', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'b09b3fb8-a1f2-4d13-9763-9155c8ea551d'	System	21 Mar 2021 13:00:48
User entered 'No (N)'	System	21 Mar 2021 13:00:48

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f15e254a0935b5a)', Time: '2021-03-21T09:00:46-04:00', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'b09b3fb8-a1f2-4d13-9763-9155c8ea551d'	System	21 Mar 2021 13:00:48
User entered '21 Mar 2021 09:00:46'	System	21 Mar 2021 13:00:48

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 09:27:37

US3662116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:58

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 (7f15e254a0935b5a)', Time: '2021-03-28T18:03:52-04:00', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '72b8223e-fa45-4083-8c5b-64c85b3915e5'	System	28 Mar 2021 22:10:18
User entered 'No (N)'	System	28 Mar 2021 22:10:18

US3662116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:58

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 (7f15e254a0935b5a)', Time: '2021-03-28T18:03:54-04:00', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '72b8223e-fa45-4083-8c5b-64c85b3915e5'	System	28 Mar 2021 22:10:18
User entered 'No (N)'	System	28 Mar 2021 22:10:18

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f15e254a0935b5a)', Time: '2021-03-28T18:03:57-04:00', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '72b8223e-fa45-4083-8c5b-64c85b3915e5'	System	28 Mar 2021 22:10:18
User entered '28 Mar 2021 18:03:57'	System	28 Mar 2021 22:10:18

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 09:27:37

US3662116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:58

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 (7f15e254a0935b5a)', Time: '2021-04-07T09:25:21-04:00', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '3c8a9872-36bf-4f31-b2ee-307cdfddcd9e'	System	07 Apr 2021 13:25:29
User entered 'No (N)'	System	07 Apr 2021 13:25:29

US3662116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:58

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 (7f15e254a0935b5a)', Time: '2021-04-07T09:25:23-04:00', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '3c8a9872-36bf-4f31-b2ee-307cdfddcd9e'	System	07 Apr 2021 13:25:29
User entered 'No (N)'	System	07 Apr 2021 13:25:29

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f15e254a0935b5a)', Time: '2021-04-07T09:25:26-04:00', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '3c8a9872-36bf-4f31-b2ee-307cdfddcd9e'	System	07 Apr 2021 13:25:29
User entered '07 Apr 2021 09:25:26'	System	07 Apr 2021 13:25:29

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 09:27:37

US3662116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:58

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 (7f15e254a0935b5a)', Time: '2021-04-11T21:40:11-04:00', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'fcec924a-5dbe-4f33-a41e-f5774e39e6da'	System	12 Apr 2021 01:40:22
User entered 'No (N)'	System	12 Apr 2021 01:40:22

US3662116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:58

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 (7f15e254a0935b5a)', Time: '2021-04-11T21:40:14-04:00', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'fcec924a-5dbe-4f33-a41e-f5774e39e6da'	System	12 Apr 2021 01:40:22
User entered 'No (N)'	System	12 Apr 2021 01:40:22

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f15e254a0935b5a)', Time: '2021-04-11T21:40:19-04:00', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'fcec924a-5dbe-4f33-a41e-f5774e39e6da'	System	12 Apr 2021 01:40:22
User entered '11 Apr 2021 21:40:19'	System	12 Apr 2021 01:40:22

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 09:27:37

US3662116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:58

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 (7f15e254a0935b5a)', Time: '2021-04-18T14:06:35-04:00', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '556d5881-2699-4dd5-8445-a7c1191fd410'	System	18 Apr 2021 18:06:46
User entered 'No (N)'	System	18 Apr 2021 18:06:46

US3662116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:58

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 (7f15e254a0935b5a)', Time: '2021-04-18T14:06:38-04:00', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '556d5881-2699-4dd5-8445-a7c1191fd410'	System	18 Apr 2021 18:06:46
User entered 'No (N)'	System	18 Apr 2021 18:06:46

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f15e254a0935b5a)', Time: '2021-04-18T14:06:42-04:00', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '556d5881-2699-4dd5-8445-a7c1191fd410'	System	18 Apr 2021 18:06:46
User entered '18 Apr 2021 14:06:42'	System	18 Apr 2021 18:06:46

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 09:27:37

US3662116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:58

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 (7f15e254a0935b5a)', Time: '2021-04-28T05:22:31-04:00', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '9139d8ec-77dd-4c08-932f-c008ca17dc58'	System	28 Apr 2021 20:33:52
User entered 'No (N)'	System	28 Apr 2021 20:33:52

US3662116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:58

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 (7f15e254a0935b5a)', Time: '2021-04-28T05:22:34-04:00', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '9139d8ec-77dd-4c08-932f-c008ca17dc58'	System	28 Apr 2021 20:33:52
User entered 'No (N)'	System	28 Apr 2021 20:33:52

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f15e254a0935b5a)', Time: '2021-04-28T05:22:37-04:00', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '9139d8ec-77dd-4c08-932f-c008ca17dc58'	System	28 Apr 2021 20:33:52
User entered '28 Apr 2021 05:22:37'	System	28 Apr 2021 20:33:52

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 09:27:37

US3662116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:58

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 (7f15e254a0935b5a)', Time: '2021-05-03T09:18:46-04:00', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'b2fbcf99-e9dc-4295-a958-804463e4a96a'	System	03 May 2021 13:18:55
User entered 'No (N)'	System	03 May 2021 13:18:55

US3662116

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:24:58

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 (7f15e254a0935b5a)', Time: '2021-05-03T09:18:48-04:00', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'b2fbcf99-e9dc-4295-a958-804463e4a96a'	System	03 May 2021 13:18:55
User entered 'No (N)'	System	03 May 2021 13:18:55

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f15e254a0935b5a)', Time: '2021-05-03T09:18:51-04:00', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: 'b2fbcf99-e9dc-4295-a958-804463e4a96a'	System	03 May 2021 13:18:55
User entered '03 May 2021 09:18:51'	System	03 May 2021 13:18:55

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '13 Nov 2022 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '17 Nov 2022 23:59'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '20 Nov 2022 00:01'	System	20 Nov 2020 09:27:37

US3662116
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:24:58
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:27:37
Amendment Manager: User entered '24 Nov 2022 23:59'	System	20 Nov 2020 09:27:37

US3662116

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:24:58

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)	25 Apr 2021 01:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f15e254a0935b5a)', Time: '2021-03-01T06:24:26-05:00', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '40fc98f3-b89f-4426-8e40-302783ee59ff'	System	01 Mar 2021 11:24:40
User entered 'No (N)'	System	01 Mar 2021 11:24:40

US3662116
Folder: Cosmetic Injections and Dermal Fillers
Form: Cosmetic Injection_ Dermal Filler eDiary (1)
Generated On: 10 Jun 2021 09:24:58
Date & Time of Submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:46:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7f15e254a0935b5a)', Time: '2021-03-01T06:24:33-05:00', User OID: 'PatientReportedOutcome (US3662116)', ODM File OID: '40fc98f3-b89f-4426-8e40-302783ee59ff'	System	01 Mar 2021 11:24:40
User entered '01 Mar 2021 06:24:33'	System	01 Mar 2021 11:24:40

US3662116
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:58
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 20:28:31
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	11 Dec 2020 19:18:06

US3662116
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:58
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 20:28:31
User entered '11 Dec 2020'	Angela Snyder (b) (4) (b) (4)	11 Dec 2020 19:18:06

US3662116
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:58
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 20:28:31
User entered 'Contact Made (CONTACT MADE)'	Angela Snyder (b) (4) (b) (4)	11 Dec 2020 19:18:06

US3662116
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:58
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 20:28:31
User entered empty.	Angela Snyder (b) (4) (b) (4)	11 Dec 2020 19:18:06

US3662116
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:24:58
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 20:28:47
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	11 Dec 2020 19:18:12

US3662116
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:24:58
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 10:43:30
User entered '1'	System	11 Dec 2020 19:18:12

US3662116
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:58
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:56:46
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:10:06
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	15 Jan 2021 18:20:51

US3662116
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:58
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:56:46
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:10:06
User entered '14 Jan 2021'	Angela Snyder (b) (4) (b) (4)	15 Jan 2021 18:20:51

US3662116
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:58
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:56:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:10:06
User entered 'Contact Made (CONTACT MADE)'	Angela Snyder (b) (4)	15 Jan 2021 18:20:51

US3662116
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:58
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:56:46
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:10:06
User entered empty.	Angela Snyder (b) (4) (b) (4)	15 Jan 2021 18:20:51

FDA-CBER-2022-1614-2919974

US3662116
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:24:58
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:56:46
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:10:16
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	15 Jan 2021 18:20:56

US3662116
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:24:58
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:56:46
User entered '1'	System	15 Jan 2021 18:20:56

US3662116
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:58
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:56:46
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:16:43
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	08 Mar 2021 15:18:00

US3662116
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:58
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:56:46
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:16:43
User entered '12 Feb 2021'	Angela Snyder (b) (4) (b) (4)	08 Mar 2021 15:18:00

US3662116
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:58
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:56:46
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:16:43
User entered 'Contact Made (CONTACT MADE)'	Angela Snyder (b) (4)	08 Mar 2021 15:18:00

US3662116
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:58
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:56:46
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:16:43
User entered empty.	Angela Snyder (b) (4) (b) (4)	08 Mar 2021 15:18:00

FDA-CBER-2022-1614-2919980

US3662116
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:24:58
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:56:46
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:16:48
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	08 Mar 2021 15:18:05

US3662116
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:24:58
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:56:46
User entered '1'	System	08 Mar 2021 15:18:05

US3662116
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:58
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:56:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:51:23
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	15 Mar 2021 13:40:46

US3662116
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:58
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:56:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:51:23
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '15 Mar 2021'	Angela Snyder (b) (4) (b) (4)	15 Mar 2021 13:40:46

US3662116
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:58
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:56:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:51:23
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Contact Made (CONTACT MADE)'	Angela Snyder (b) (4) (b) (4)	15 Mar 2021 13:40:46

US3662116
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:24:58
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:56:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:51:23
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	15 Mar 2021 13:40:46

FDA-CBER-2022-1614-2919986

US3662116
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:24:58
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:56:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:51:28
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	15 Mar 2021 13:40:52

US3662116
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:24:58
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 22:56:46
User entered '1'	System	15 Mar 2021 13:40:52

US3662116
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:24:58
Was this visit performed?

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	28 Apr 2021 13:41:38
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	20 Apr 2021 15:35:44

US3662116
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:24:58
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	28 Apr 2021 13:41:38
User entered '20 Apr 2021'	Angela Snyder (b) (4) (b) (4)	20 Apr 2021 15:35:44

US3662116
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:24:58
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	28 Apr 2021 13:41:38
User entered 'Clinic (Clinic)'	Angela Snyder (b) (4) (b) (4)	20 Apr 2021 15:35:44

US3662116
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:24:58
Folder OID

Audit	User	Time (GMT)
User entered 'VISIT4'	System	20 Apr 2021 15:35:44

US3662116
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:58
Were vital signs assessed?

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	28 Apr 2021 13:41:38
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	20 Apr 2021 15:36:30

US3662116
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:58
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	28 Apr 2021 13:41:38
User entered '20 Apr 2021'	Angela Snyder (b) (4) (b) (4)	20 Apr 2021 15:36:30

FDA-CBER-2022-1614-2919994

US3662116
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:58
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	28 Apr 2021 13:41:38
User entered '10:45'	Angela Snyder (b) (4) (b) (4)	20 Apr 2021 15:36:30

US3662116
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:58
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
User entered '20 Apr 2021 10:45'	System	20 Apr 2021 15:36:30

US3662116
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:58
Temperature *(xxx.x)*

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	28 Apr 2021 13:41:38
User entered '97.9' F	Angela Snyder (b) (4) (b) (4)	20 Apr 2021 15:36:30

US3662116
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:58
Route of measurement

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	28 Apr 2021 13:41:38
User entered 'Other (Other)'	Angela Snyder (b) (4) (b) (4)	20 Apr 2021 15:36:30

US3662116
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:58
If Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	28 Apr 2021 13:41:38
User entered 'infrared thermometer'	Angela Snyder (b) (4) (b) (4)	20 Apr 2021 15:36:30

US3662116
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:58
Pulse *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	28 Apr 2021 13:41:38
User entered '87'	Angela Snyder (b) (4) (b) (4)	20 Apr 2021 15:36:30

US3662116
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:58
Pulse units

Audit	User	Time (GMT)
User entered 'bpm'	System	20 Apr 2021 15:36:30

US3662116
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:58
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	28 Apr 2021 13:41:38
User entered '16'	Angela Snyder (b) (4) (b) (4)	20 Apr 2021 15:36:30

US3662116
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:58
Respiratory Rate units

Audit	User	Time (GMT)
User entered 'breaths/min'	System	20 Apr 2021 15:36:30

FDA-CBER-2022-1614-2920003

US3662116
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:58
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	28 Apr 2021 13:41:38
User entered '107'	Angela Snyder (b) (4) (b) (4)	20 Apr 2021 15:36:30

US3662116
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:58
Systolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Apr 2021 15:36:30

US3662116
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:58
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	28 Apr 2021 13:41:38
User entered '85'	Angela Snyder (b) (4) (b) (4)	20 Apr 2021 15:36:30

FDA-CBER-2022-1614-2920006

US3662116
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:24:58
Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Apr 2021 15:36:30

US3662116
Folder: Visit 4 Day 209 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:24:58
Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	28 Apr 2021 13:41:38
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	20 Apr 2021 15:36:41

US3662116
Folder: Visit 4 Day 209 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:24:58
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	28 Apr 2021 13:41:38
User entered empty.	Angela Snyder (b) (4) (b) (4)	20 Apr 2021 15:36:41

US3662116
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:24:58
Was the sample collected?

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	28 Apr 2021 13:41:38
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	20 Apr 2021 15:36:56

US3662116
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:24:58
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	28 Apr 2021 13:41:38
User entered '20 Apr 2021'	Angela Snyder (b) (4) (b) (4)	20 Apr 2021 15:36:56

FDA-CBER-2022-1614-2920011

US3662116
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:24:58
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	28 Apr 2021 13:41:38
User entered '10:51'	Angela Snyder (b) (4) (b) (4)	20 Apr 2021 15:36:56

US3662116
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:24:58
Collection date and time (derived)

Audit	User	Time (GMT)
User entered '20 Apr 2021 10:51'	System	20 Apr 2021 15:36:56

US3662116
Folder: Visit 4 Day 209 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:24:58
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	28 Apr 2021 13:41:38
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	20 Apr 2021 15:37:01

US3662116
Folder: Visit 4 Day 209 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:24:58
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 15:37:01

US3662116
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:24:58
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:11:14
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:50:53

US3662116
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:24:58
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:11:14
User entered '19 Jan 2021'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:50:53

US3662116
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:24:58
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:11:14
User entered 'Clinic (Clinic)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:50:53

US3662116
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:24:58
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered 'UNBLND_DECIDE'	System	19 Jan 2021 16:50:53

US3662116
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:24:58
Date of updated informed consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:11:23
User entered '19 Jan 2021'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:51:16

US3662116
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:24:58
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:11:23
User entered '0'	Angela Snyder (b) (4)	09 Mar 2021 16:27:03
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 09:16:40

US3662116
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:24:58
Was the participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:11:23
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:51:16

US3662116
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:24:58
Under what version of the Protocol was the Participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:11:23
User entered 'Amendment 6 or later (Amendment 6 or later)'	Angela Snyder (b) (4)	09 Mar 2021 16:27:03
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 09:16:40

US3662116
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:24:58
Date of unblinding *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:11:23
User entered '19 Jan 2021'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:51:16

US3662116
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:24:58
Participant randomization assignment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:11:23
User entered 'mRNA-1273 (mRNA-1273)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:51:16

US3662116
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:24:58
Actual Dose 1

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:11:23
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 04:53:22
User entered 'mRNA-1273 (mRNA-1273)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:51:16

US3662116
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:24:58
Actual Dose 2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:11:23
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 04:53:22
User entered 'mRNA-1273 (mRNA-1273)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:51:16

US3662116
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:24:58
Will participant receive mRNA-1273?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:11:23
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:51:16

US3662116
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:24:58
Placebo Only Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered empty.	System	19 Jan 2021 16:51:16

FDA-CBER-2022-1614-2920029

US3662116
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:24:58
Continuing with mRNA-1273

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered empty.	System	19 Jan 2021 16:51:16

FDA-CBER-2022-1614-2920030

US3662116
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:24:58
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:11:40
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:51:36

US3662116
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:24:58
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:11:40
User entered '19 Jan 2021'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:51:36

US3662116
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:24:58
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:11:40
User entered '09:15'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:51:36

US3662116
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:24:58
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered '19 Jan 2021 09:15'	System	19 Jan 2021 16:51:36

US3662116
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 10 Jun 2021 09:24:58
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:11:46
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:51:48

US3662116
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 10 Jun 2021 09:24:58
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:11:46
User entered '19 Jan 2021'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:51:48

US3662116
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 10 Jun 2021 09:24:58
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:11:46
User entered '09:10'	Angela Snyder (b) (4) (b) (4)	19 Jan 2021 16:51:48

US3662116
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 10 Jun 2021 09:24:58
Collection Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:34:05
User entered '19 Jan 2021 09:10'	System	19 Jan 2021 16:51:48

FDA-CBER-2022-1614-2920038

US3662116
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 10 Jun 2021 09:24:58
Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:26:54
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 20:29:38
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	11 Dec 2020 19:19:55

US3662116
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:24:58
Adverse event

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 20:30:08
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Hyperglycaemic conditions NEC, PT: Glucose tolerance impaired, LLT: Pre-diabetes - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Dec 2020 19:22:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Dec 2020 19:22:54
Data point term sent to Coder	System	11 Dec 2020 19:22:07
User entered 'PRE-DIABETES'	Angela Snyder (b) (4) (b) (4)	11 Dec 2020 19:21:10

US3662116
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:24:58
Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 20:30:08
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	11 Dec 2020 19:21:10

US3662116
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:24:58
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 20:30:08
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	11 Dec 2020 19:21:10

US3662116
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:24:58
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 20:30:08
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	11 Dec 2020 19:21:10

US3662116
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:24:58
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 20:30:08
User entered '16 Nov 2020'	Angela Snyder (b) (4) (b) (4)	11 Dec 2020 19:21:10

US3662116
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:24:58
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 20:30:08
User entered empty.	Angela Snyder (b) (4) (b) (4)	11 Dec 2020 19:21:10

US3662116
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:24:58
AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	11 Dec 2020 19:21:10

US3662116
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:24:58
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 20:30:08
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	11 Dec 2020 19:21:10

US3662116
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:24:58
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 20:30:08
User entered empty.	Angela Snyder (b) (4) (b) (4)	11 Dec 2020 19:21:10

US3662116
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:24:58
End time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 20:30:08
User entered empty.	Angela Snyder (b) (4) (b) (4)	11 Dec 2020 19:21:10

US3662116
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:24:58
AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	11 Dec 2020 19:21:10

US3662116
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:24:58
Severity

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 20:30:08
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Angela Snyder (b) (4) (b) (4)	11 Dec 2020 19:21:10

US3662116
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:24:58
Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 20:30:08
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	11 Dec 2020 19:21:10

US3662116
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:24:58
Death

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 20:30:08
User entered '0'	Angela Snyder (b) (4) (b) (4)	11 Dec 2020 19:21:10

US3662116
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:24:58
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 20:30:08
User entered '0'	Angela Snyder (b) (4) (b) (4)	11 Dec 2020 19:21:10

US3662116
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:24:58
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 20:30:08
User entered '0'	Angela Snyder (b) (4) (b) (4)	11 Dec 2020 19:21:10

US3662116
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:24:58
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 20:30:08
User entered empty.	Angela Snyder (b) (4) (b) (4)	11 Dec 2020 19:21:10

US3662116
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:24:58
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 20:30:08
User entered empty.	Angela Snyder (b) (4) (b) (4)	11 Dec 2020 19:21:10

US3662116
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:24:58
Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 20:30:08
User entered empty.	Angela Snyder (b) (4) (b) (4)	11 Dec 2020 19:21:10

US3662116
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:24:58
Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 20:30:08
User entered empty.	Angela Snyder (b) (4) (b) (4)	11 Dec 2020 19:21:10

US3662116
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:24:58
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 20:30:08
User entered '0'	Angela Snyder (b) (4) (b) (4)	11 Dec 2020 19:21:10

US3662116
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:24:58
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 20:30:08
User entered '0'	Angela Snyder (b) (4) (b) (4)	11 Dec 2020 19:21:10

US3662116
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:24:58
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 20:30:08
User entered '0'	Angela Snyder (b) (4) (b) (4)	11 Dec 2020 19:21:10

US3662116
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:24:58
Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 20:30:08
User entered 'Not Related (NOT RELATED)'	Angela Snyder (b) (4) (b) (4)	11 Dec 2020 19:21:10

US3662116
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:24:58
Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 20:30:08
User entered 'Not Related (NOT RELATED)'	Angela Snyder (b) (4) (b) (4)	11 Dec 2020 19:21:10

US3662116
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:24:58
Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 20:30:08
User entered 'Not Applicable (NOT APPLICABLE)'	Angela Snyder (b) (4) (b) (4)	11 Dec 2020 19:21:10

US3662116
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:24:58
None

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 20:30:08
User entered '0'	Angela Snyder (b) (4) (b) (4)	11 Dec 2020 19:21:10

US3662116
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:24:58
Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 20:30:08
User entered '1'	Angela Snyder (b) (4) (b) (4)	11 Dec 2020 19:21:10

US3662116
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:24:58
Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 20:30:08
User entered '0'	Angela Snyder (b) (4) (b) (4)	11 Dec 2020 19:21:10

US3662116
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:24:58
Outcome

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 20:30:08
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Angela Snyder (b) (4) (b) (4)	11 Dec 2020 19:21:10

US3662116
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:24:58
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 20:30:08
User entered empty.	Angela Snyder (b) (4) (b) (4)	11 Dec 2020 19:21:10

US3662116
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:24:58
Narrative

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 20:30:08
User entered empty.	Angela Snyder (b) (4) (b) (4)	11 Dec 2020 19:21:10

FDA-CBER-2022-1614-2920071

US3662116
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:24:58
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '0'	System	11 Dec 2020 19:21:10

US3662116
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:24:58
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	11 Dec 2020 19:21:10

US3662116
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:24:58
AEID

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:18:09
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:46:51
User entered 'USA-US088-2021-mRNA-1273-P301000009'	System	16 Feb 2021 14:46:48
User entered 'New'	(b) (4), (b) (6)	16 Feb 2021 14:46:48

US3662116
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:24:58
Adverse event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:56:33
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal stenosis and obstruction, HLT: Duodenal and small intestinal stenosis and obstruction, PT: Small intestinal obstruction, LLT: Small bowel obstruction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:10:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:10:01
Data point term sent to Coder	System	18 Mar 2021 22:08:34
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal stenosis and obstruction, HLT: Duodenal and small intestinal stenosis and obstruction, PT: Small intestinal obstruction, LLT: Small bowel obstruction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Feb 2021 20:29:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Feb 2021 20:29:58
Data point term sent to Coder	System	12 Feb 2021 20:29:25
User entered 'small bowel obstruction'	michelle saemann (b) (4) (b) (4)	12 Feb 2021 20:29:22

US3662116
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:24:58
Was this a medically-attended AE?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:56:33
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Yes (Y)'	michelle saemann (b) (4) (b) (4)	12 Feb 2021 20:29:22

US3662116
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:24:58
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:56:33
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	michelle saemann (b) (4) (b) (4)	12 Feb 2021 20:29:22

US3662116
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:24:58
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:56:33
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	michelle saemann (b) (4) (b) (4)	12 Feb 2021 20:29:22

US3662116
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:24:58
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 14:17:28
User closed query 'PV Query: As per the narrative, the subject presented to the emergency on 11 Feb 2021 with abdominal pain which started a day prior in evening. Since the event onset date should be the date when the first signs/symptoms appeared, therefore kindly consider updating the event onset date accordingly. ' (Site from Safety).	(b) (4), (b) (6)	07 Apr 2021 13:56:52
Query 'PV Query: As per the narrative, the subject presented to the emergency on 11 Feb 2021 with abdominal pain which started a day prior in evening. Since the event onset date should be the date when the first signs/symptoms appeared, therefore kindly consider updating the event onset date accordingly. ' answered with 'updated' (Site from Safety).	michelle saemann (b) (4) (b) (4)	06 Apr 2021 12:40:25
DataPoint Un-verified.	michelle saemann (b) (4) (b) (4)	06 Apr 2021 12:40:19
Signature has been broken.	michelle saemann (b) (4) (b) (4)	06 Apr 2021 12:40:19
User entered '10 Feb 2021' reason for change: Per Query Resolution	michelle saemann (b) (4) (b) (4)	06 Apr 2021 12:40:19
User opened query 'PV Query: As per the narrative, the subject presented to the emergency on 11 Feb 2021 with abdominal pain which started a day prior in evening. Since the event onset date should be the date when the first signs/symptoms appeared, therefore kindly consider updating the event onset date accordingly. ' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 11:58:22
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:56:33
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '11 Feb 2021'	michelle saemann (b) (4) (b) (4)	12 Feb 2021 20:29:22

US3662116
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:24:58
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:56:33
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	michelle saemann (b) (4) (b) (4)	12 Feb 2021 20:29:22

US3662116
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:24:58
AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	12 Feb 2021 20:29:22

US3662116
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:24:58
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:56:33
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	23 Feb 2021 16:11:55
User entered 'No (N)' reason for change: Data Entry Error	MaKayla Bishop (b) (4) (b) (4)	23 Feb 2021 16:11:55
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	23 Feb 2021 16:11:36
User entered 'Yes (Y)'	michelle saemann (b) (4) (b) (4)	12 Feb 2021 20:29:22

US3662116
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:24:58
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from DM).	(b) (4), (b) (6)	27 Apr 2021 17:47:52
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Please clarify what you are asking. . There is an end date entered here ' (Site from DM).	michelle saemann (b) (4) (b) (4)	26 Apr 2021 18:42:01
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 18:27:47
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:56:33
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	23 Feb 2021 16:11:36
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	23 Feb 2021 16:11:36
User entered '16 Feb 2021' reason for change: Data Entry Error	MaKayla Bishop (b) (4) (b) (4)	23 Feb 2021 16:11:36
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	23 Feb 2021 16:11:13
User entered empty.	michelle saemann (b) (4) (b) (4)	12 Feb 2021 20:29:22

US3662116
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:24:58
End time *(00:00-23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:56:33
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	michelle saemann (b) (4) (b) (4)	12 Feb 2021 20:29:22

US3662116
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:24:58
AE End Date and Time (derived)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 19:38:20
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 19:29:45
User entered empty.	System	12 Feb 2021 20:29:22

US3662116
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:24:58
Severity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:56:33
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Grade 3/Severe (Grade 3/Severe)'	michelle saemann (b) (4) (b) (4)	12 Feb 2021 20:29:22

US3662116
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:24:58
Is the adverse event serious?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:56:33
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Yes (Y)'	michelle saemann (b) (4) (b) (4)	12 Feb 2021 20:29:22

US3662116
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:24:58
Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:56:33
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	michelle saemann (b) (4) (b) (4)	12 Feb 2021 20:29:22

US3662116
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:24:58
Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:56:33
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	michelle saemann (b) (4) (b) (4)	12 Feb 2021 20:29:22

US3662116
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:24:58
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:56:33
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	24 Feb 2021 03:41:45
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'will update as information is received. ' (Site from System).	michelle saemann (b) (4)	12 Feb 2021 20:29:57
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	12 Feb 2021 20:29:22
User entered '1'	michelle saemann (b) (4)	12 Feb 2021 20:29:22

US3662116
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:24:58
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:56:33
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '11 Feb 2021'	michelle saemann (b) (4) (b) (4)	12 Feb 2021 20:29:22

US3662116
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:24:58
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:56:33
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	23 Feb 2021 21:19:43
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	23 Feb 2021 21:19:40
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'Email sent 02.23.2021 @1539' (Site from Safety).	MaKayla Bishop (b) (4) (b) (4)	23 Feb 2021 20:51:50
User entered '16 Feb 2021' reason for change: Data Entry Error	MaKayla Bishop (b) (4) (b) (4)	23 Feb 2021 16:08:59
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'discharge date provided. ' (Site from Safety).	MaKayla Bishop (b) (4) (b) (4)	23 Feb 2021 16:01:57
User entered '17 Feb 2021' reason for change: Data Entry Error	MaKayla Bishop (b) (4) (b) (4)	23 Feb 2021 16:01:04
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 19:31:02
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 19:29:23
User entered empty.	michelle saemann (b) (4) (b) (4)	12 Feb 2021 20:29:22

US3662116
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:24:58
Admitted to ICU?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:56:33
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	michelle saemann (b) (4) (b) (4)	12 Feb 2021 20:29:22

US3662116
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:24:58
Number of Days in ICU

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:56:33
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	michelle saemann (b) (4) (b) (4)	12 Feb 2021 20:29:22

US3662116
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:24:58
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:56:33
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	michelle saemann (b) (4) (b) (4)	12 Feb 2021 20:29:22

US3662116
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:24:58
Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:56:33
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	michelle saemann (b) (4) (b) (4)	12 Feb 2021 20:29:22

US3662116
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:24:58
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:56:33
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	michelle saemann (b) (4) (b) (4)	12 Feb 2021 20:29:22

US3662116
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:24:58
Relationship to investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:56:33
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Not Related (NOT RELATED)'	michelle saemann (b) (4) (b) (4)	12 Feb 2021 20:29:22

US3662116
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:24:58
Relationship to Study Procedure

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:56:33
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Not Related (NOT RELATED)'	michelle saemann (b) (4) (b) (4)	12 Feb 2021 20:29:22

US3662116
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:24:58
Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:56:33
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
User entered 'Not Applicable (NOT APPLICABLE)'	michelle saemann (b) (4)	12 Feb 2021 20:29:22

US3662116
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:24:58
None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:56:33
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	michelle saemann (b) (4) (b) (4)	12 Feb 2021 20:29:22

US3662116
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:24:58
Concomitant Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:56:33
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '1'	michelle saemann (b) (4) (b) (4)	12 Feb 2021 20:29:22

US3662116
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:24:58
Concomitant Procedure

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:56:33
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '1'	michelle saemann (b) (4) (b) (4)	12 Feb 2021 20:29:22

US3662116
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:24:58
Outcome

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:56:33
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:19:48
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'resolved. ' (Site from Safety).	MaKayla Bishop (b) (4) (b) (4)	23 Feb 2021 20:52:05
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	MaKayla Bishop (b) (4) (b) (4)	23 Feb 2021 16:11:13
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 19:30:05
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	michelle saemann (b) (4) (b) (4)	12 Feb 2021 20:29:22

US3662116
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:24:58
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:56:33
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	michelle saemann (b) (4) (b) (4)	12 Feb 2021 20:29:22

US3662116
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:24:58
Narrative

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:54
User closed query 'Per DM CLR: Narrative = GASTROGRAFIN. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Mar 2021 07:57:15
User closed query 'Per CDM:RQ: Response provided as 'added to MH per PI instruction' However, MH has not been updated with this medical condition. Please confirm and update appropriately. Thank you ' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 07:56:34
User closed query 'Per DM CLR: Narrative = HYPOKALEMIA. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 07:56:06
Query 'Per DM CLR: Narrative = GASTROGRAFIN. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'med log updated' (Site from DM).	michelle saemann (b) (4) (b) (4)	25 Mar 2021 19:04:55
Query 'Per DM CLR: Narrative = HYPOKALEMIA. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'added to AE log' (Site from DM).	michelle saemann (b) (4) (b) (4)	25 Mar 2021 18:56:39
Query 'Per CDM:RQ: Response provided as 'added to MH per PI instruction' However, MH has not been updated with this medical condition. Please confirm and update appropriately. Thank you ' answered with 'MH updated' (Site from DM).	michelle saemann (b) (4) (b) (4)	25 Mar 2021 18:45:55
User closed query 'Per DM CLR: Narrative = URINE IS PENDING. 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)	25 Mar 2021 13:13:31
User closed query 'Per DM CLR: Narrative = TROPONIN. 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)	25 Mar 2021 13:12:43

US3662116
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:24:58
Narrative

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Narrative = LABS. 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)	25 Mar 2021 13:11:13
User closed query 'Per DM CLR: Narrative = EKG. 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)	25 Mar 2021 13:08:54
User closed query 'Per DM CLR: Narrative = SBO IMAGING. 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)	25 Mar 2021 13:07:33
User opened query 'Per CDM:RQ: Response provided as 'added to MH per PI instruction' However, MH has not been updated with this medical condition. Please confirm and update appropriately. Thank you ' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 13:04:17
User closed query 'Per DM CLR: Narrative = RUQ INCISIONAL HERNIA. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 13:04:17
User closed query 'Per DM CLR: Narrative = PATIENT HAS A HISTORY OF ABDOMINAL AORTIC DISSECTION. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 12:53:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:56:33
Query 'Per DM CLR: Narrative = SBO IMAGING. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'comma added to narrative. conproc that were completed have been entered' (Site from DM).	michelle saemann (b) (4) (b) (4)	24 Mar 2021 13:33:52

US3662116
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:24:58
Narrative

Audit	User	Time (GMT)
Query 'Per DM CLR: Narrative = RUQ INCISIONAL HERNIA. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'added to MH per PI instruction' (Site from DM).	michelle saemann (b) (4) (b) (4)	24 Mar 2021 13:33:26
Signature has been broken.	michelle saemann (b) (4) (b) (4)	24 Mar 2021 13:33:12

US3662116
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:24:58
Narrative

Audit	User	Time (GMT)
User entered 'PATIENT PRESENTS COMPLAINING OF EPIGASTRIC ABDOMINAL PAIN THAT STARTED LAST EVENING. SHE REPORTS THAT THIS CONTINUED TO GET WORSE, WHICH PROMPTED HER TO COME TO THE ED FOR EVALUATION. SHE ALSO REPORTS SOME NAUSEA WITH 3 EPISODES OF EMESIS. SHE REPORTS THAT HER LAST BOWEL MOVEMENT WAS THIS MORNING AND IT WAS SOFT. SHE DENIES ANY FEVERS, NO CHEST PAIN, NO TROUBLE BREATHING. PATIENT HAS HAD MULTIPLE PREVIOUS ABDOMINAL SURGERIES. SHE IS AFEBRILE AND HEMODYNAMICALLY STABLE. EKG SHOWS STABLE FINDINGS FROM PREVIOUSLY WITHOUT ST ELEVATIONS OR DEPRESSIONS. LABS ARE OVERALL UNREMARKABLE. HIGH SENSITIVITY TROPONIN <3, STABLE ON REPEAT. URINE IS PENDING. CHEST X-RAY IS NEGATIVE. ABDOMINAL X-RAY SHOWS AN INDETERMINATE BOWEL GAS PATTERN. PATIENT HAS A HISTORY OF ABDOMINAL AORTIC DISSECTION, SO CT ANGIO WAS OBTAINED TO FURTHER ASSESS FOR POSSIBLE CAUSES OF HER PAIN. THIS SHOWED STABLE ABDOMINAL AORTIC DISSECTION IN ADDITION TO SMALL BOWEL OBSTRUCTION WITH TO TRANSITION POINTS AT THE WIDEMOUTH HERNIA. ACS WAS CONSULTED AND CAME TO SEE THE PATIENT. AND PLACED AN NG TUBE AND WOULD LIKE TO ADMIT THE PATIENT OTHER SERVICE FOR FURTHER MANAGEMENT. AT THIS TIME THE PATIENT HAS BEEN ADMITTED TO ACS FOR FURTHER EVALUATION AND MANAGEMENT OF SMALL BOWEL OBSTRUCTION. 02.17.2021 UPDATE ABDOMINAL PAIN CONCERN FOR SBO, IMAGING WITH CONCERN AT SITE OF RUQ INCISIONAL	michelle saemann (b) (4) (b) (4)	24 Mar 2021 13:33:12

Audit	User	Time (GMT)
HERNIA. NG PLACED AND GASTROGRAFIN TRIAL INITIATED WITH PROGRESSION TO COLON. NG TUBE REMOVED AFTER PATIENT PASSED GRAVITY TRIAL ON 2/12. SHE WAS STARTED ON CLEARS AND ADVANCED AS TOLERATED. TOLERATING REGULAR DIET WITH BOWEL FUNCTION AT TIME OF DISCHARGE. STARTED ON BOWEL REGIMEN AT DISCHARGE GIVEN DAILY USE OF TYLENOL-3 PRIOR TO ADMISSION. HYPOKALEMIA REPLETED AND RESOLVED.' reason for change: New Information		
Query 'Per DM CLR: Narrative = PATIENT HAS A HISTORY OF ABDOMINAL AORTIC DISSECTION. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' answered with 'added to MH' (Site from DM).	michelle saemann (b) (4) (b) (4)	24 Mar 2021 13:32:09
Query 'Per DM CLR: Narrative = URINE IS PENDING. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Per study team, conproc form not required for labs' (Site from DM).	michelle saemann (b) (4) (b) (4)	24 Mar 2021 13:31:58
Query 'Per DM CLR: Narrative = LABS. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Per study team, conproc form not required for labs' (Site from DM).	michelle saemann (b) (4) (b) (4)	24 Mar 2021 13:31:51
Query 'Per DM CLR: Narrative = TROPONIN. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Per study team, conproc form not required for labs' (Site from DM).	michelle saemann (b) (4) (b) (4)	24 Mar 2021 13:31:36
Query 'Per DM CLR: Narrative = EKG. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'ConProc form entered' (Site from DM).	michelle saemann (b) (4) (b) (4)	24 Mar 2021 13:31:13

US3662116
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:24:58
Narrative

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Narrative = HYPOKALEMIA. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 11:26:52
User opened query 'Per DM CLR: Narrative = GASTROGRAFIN. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 11:26:45
User opened query 'Per DM CLR: Narrative = RUQ INCISIONAL HERNIA. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 11:26:39
User opened query 'Per DM CLR: Narrative = SBO IMAGING. 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)	19 Mar 2021 11:26:33
User opened query 'Per DM CLR: Narrative = PATIENT HAS A HISTORY OF ABDOMINAL AORTIC DISSECTION. However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 11:26:27
User opened query 'Per DM CLR: Narrative = URINE IS PENDING. 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)	19 Mar 2021 11:26:21
User opened query 'Per DM CLR: Narrative = TROPONIN. 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)	19 Mar 2021 11:26:16
User opened query 'Per DM CLR: Narrative = LABS. 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)	19 Mar 2021 11:26:11

US3662116
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:24:58
Narrative

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Narrative = EKG. 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)	19 Mar 2021 11:26:06
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:19:55
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)	23 Feb 2021 21:19:51
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 'please see Email sent 02.23.2021 @1539 for COVID-19 results. ' (Site from Safety).	MaKayla Bishop (b) (4) (b) (4)	23 Feb 2021 20:52:36
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'Email sent 02.23.2021 @1539' (Site from Safety).	MaKayla Bishop (b) (4) (b) (4)	23 Feb 2021 20:52:11
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 19:30:25

US3662116
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:24:58
Narrative

Audit	User	Time (GMT)
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)	22 Feb 2021 19:28:22

US3662116
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:24:58
Narrative

Audit	User	Time (GMT)
User entered 'PATIENT PRESENTS COMPLAINING OF EPIGASTRIC ABDOMINAL PAIN THAT STARTED LAST EVENING. SHE REPORTS THAT THIS CONTINUED TO GET WORSE, WHICH PROMPTED HER TO COME TO THE ED FOR EVALUATION. SHE ALSO REPORTS SOME NAUSEA WITH 3 EPISODES OF EMESIS. SHE REPORTS THAT HER LAST BOWEL MOVEMENT WAS THIS MORNING AND IT WAS SOFT. SHE DENIES ANY FEVERS, NO CHEST PAIN, NO TROUBLE BREATHING. PATIENT HAS HAD MULTIPLE PREVIOUS ABDOMINAL SURGERIES. SHE IS AFEBRILE AND HEMODYNAMICALLY STABLE. EKG SHOWS STABLE FINDINGS FROM PREVIOUSLY WITHOUT ST ELEVATIONS OR DEPRESSIONS. LABS ARE OVERALL UNREMARKABLE. HIGH SENSITIVITY TROPONIN <3, STABLE ON REPEAT. URINE IS PENDING. CHEST X-RAY IS NEGATIVE. ABDOMINAL X-RAY SHOWS AN INDETERMINATE BOWEL GAS PATTERN. PATIENT HAS A HISTORY OF ABDOMINAL AORTIC DISSECTION, SO CT ANGIO WAS OBTAINED TO FURTHER ASSESS FOR POSSIBLE CAUSES OF HER PAIN. THIS SHOWED STABLE ABDOMINAL AORTIC DISSECTION IN ADDITION TO SMALL BOWEL OBSTRUCTION WITH TO TRANSITION POINTS AT THE WIDEMOUTH HERNIA. ACS WAS CONSULTED AND CAME TO SEE THE PATIENT. AND PLACED AN NG TUBE AND WOULD LIKE TO ADMIT THE PATIENT OTHER SERVICE FOR FURTHER MANAGEMENT. AT THIS TIME THE PATIENT HAS BEEN ADMITTED TO ACS FOR FURTHER EVALUATION AND MANAGEMENT OF SMALL BOWEL OBSTRUCTION. 02.17.2021 update Abdominal Pain Concern for SBO Imaging with concern at site of RUQ incisional hernia. NG placed and	MaKayla Bishop (b) (4) (b) (4)	17 Feb 2021 19:17:06

Audit	User	Time (GMT)
gastrografin trial initiated with progression to colon. NG tube removed after patient passed gravity trial on 2/12. She was started on clears and advanced as tolerated. Tolerating regular diet with bowel function at time of discharge. Started on bowel regimen at discharge given daily use of Tylenol-3 prior to admission. Hypokalemia Repleted and resolved.' reason for change: Data Entry Error User entered 'Patient presents complaining of epigastric abdominal pain that started last evening. She reports that this continued to get worse, which prompted her to come to the ED for evaluation. She also reports some nausea with 3 episodes of emesis. She reports that her last bowel movement was this morning and it was soft. She denies any fevers, no chest pain, no trouble breathing. Patient has had multiple previous abdominal surgeries. She is afebrile and hemodynamically stable. EKG shows stable findings from previously without ST elevations or depressions. Labs are overall unremarkable. High sensitivity troponin <3, stable on repeat. Urine is pending. Chest x-ray is negative. Abdominal x-ray shows an indeterminate bowel gas pattern. Patient has a history of abdominal aortic dissection, so CT angio was obtained to further assess for possible causes of her pain. This showed stable abdominal aortic dissection in addition to small bowel obstruction with to transition points at the widemouth hernia. ACS was consulted and came to see the patient. And placed an NG tube and would like to admit the patient other service for further management. At this time the patient has been admitted to ACS for further evaluation and management of small bowel obstruction.'	michelle saemann (b) (4) (b) (4)	12 Feb 2021 20:29:22

FDA-CBER-2022-1614-2920115

US3662116
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:24:58
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '1'	System	12 Feb 2021 20:29:22

US3662116
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:24:58
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	12 Feb 2021 20:29:22

US3662116
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:24:58
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	12 Feb 2021 20:29:22

US3662116
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:24:58
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:29

FDA-CBER-2022-1614-2920119

US3662116
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:24:58
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:29
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Oropharyngeal pain, LLT: Sore throat - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Apr 2021 11:19:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Apr 2021 11:19:58
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:59:00
Data point term sent to Coder	System	18 Mar 2021 22:08:34
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
Data point term sent to Coder	System	22 Feb 2021 16:29:04
User entered 'sore throat due to ng tube placement'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:28:38

US3662116
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:24:58
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:29
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:59:00
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:28:38

US3662116
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:24:58
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:29
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:59:00
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:28:38

US3662116
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:24:58
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:29
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:59:00
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:28:38

US3662116
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:24:58
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:29
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:59:00
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '11 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:28:38

US3662116
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:24:58
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:29
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:59:00
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:28:38

US3662116
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:24:58
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:29
User entered empty.	System	22 Feb 2021 16:28:38

US3662116
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:24:58
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:29
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:59:00
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:28:38

US3662116
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:24:58
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:29
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:59:00
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '16 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:28:38

US3662116
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:24:58
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:29
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:59:00
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:28:38

US3662116
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:24:58
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:29
User entered empty.	System	22 Feb 2021 16:28:38

US3662116
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:24:58
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:29
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:59:00
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:28:38

US3662116
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:24:58
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:29
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:59:00
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:28:38

US3662116
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:24:58
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:29
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:59:00
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:28:38

US3662116
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:24:58
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:29
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:59:00
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:28:38

US3662116
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:24:58
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:29
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:59:00
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:28:38

US3662116
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:24:58
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:29
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:59:00
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:28:38

FDA-CBER-2022-1614-2920136

US3662116
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:24:58
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:29
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:59:00
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:28:38

US3662116
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:24:58
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:29
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:59:00
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:28:38

US3662116
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:24:58
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:29
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:59:00
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:28:38

US3662116
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:24:58
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:29
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:59:00
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:28:38

US3662116
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:24:58
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:29
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:59:00
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:28:38

US3662116
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:24:58
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:29
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:59:00
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:28:38

US3662116
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:24:58
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:29
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:59:00
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Not Related (NOT RELATED)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:28:38

US3662116
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:24:58
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:29
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:59:00
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Not Related (NOT RELATED)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:28:38

US3662116
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:24:58
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:29
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:59:00
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Not Applicable (NOT APPLICABLE)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:28:38

US3662116
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:24:58
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:29
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:59:00
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:28:38

FDA-CBER-2022-1614-2920146

US3662116
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:24:58
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:29
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:59:00
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '1'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:28:38

US3662116
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:24:58
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:29
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:59:00
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:28:38

US3662116
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:24:58
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:29
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:59:00
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:28:38

US3662116
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:24:58
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:29
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:59:00
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:28:38

US3662116
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:24:58
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:29
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:59:00
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:28:38

US3662116
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:24:58
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:29
User entered '0'	System	22 Feb 2021 16:28:38

US3662116
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:24:58
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:29
User entered '1'	System	22 Feb 2021 16:28:38

US3662116
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 09:24:58
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:29

FDA-CBER-2022-1614-2920154

US3662116
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:24:58
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:37

FDA-CBER-2022-1614-2920155

US3662116
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:24:58
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:00:12
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension worsened - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:09:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:09:38
Data point term sent to Coder	System	18 Mar 2021 22:08:35
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension worsened - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Feb 2021 16:30:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Feb 2021 16:30:59
Data point term sent to Coder	System	22 Feb 2021 16:30:05
User entered 'worsening htn'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:29:39

US3662116
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:24:58
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:00:12
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:29:39

US3662116
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:24:58
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:00:12
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:29:39

US3662116
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:24:58
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:00:12
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:29:39

US3662116
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:24:58
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:00:12
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '12 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:29:39

US3662116
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:24:58
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:00:12
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:29:39

US3662116
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:24:58
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:37
User entered empty.	System	22 Feb 2021 16:29:39

US3662116
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:24:58
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:00:12
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:29:39

US3662116
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:24:58
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:00:12
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '15 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:29:39

US3662116
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:24:58
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:00:12
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:29:39

US3662116
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:24:58
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:37
User entered empty.	System	22 Feb 2021 16:29:39

US3662116
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:24:58
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:00:12
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:29:39

US3662116
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:24:58
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:00:12
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:29:39

US3662116
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:24:58
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:00:12
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:29:39

US3662116
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:24:58
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:00:12
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:29:39

US3662116
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:24:58
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:00:12
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:29:39

US3662116
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:24:58
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:00:12
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:29:39

US3662116
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:24:58
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:00:12
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:29:39

US3662116
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:24:58
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:00:12
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:29:39

US3662116
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:24:58
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:00:12
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:29:39

US3662116
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:24:58
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:00:12
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:29:39

US3662116
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:24:58
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:00:12
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:29:39

US3662116
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:24:58
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:00:12
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:29:39

US3662116
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:24:58
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:00:12
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Not Related (NOT RELATED)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:29:39

US3662116
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:24:58
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:00:12
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Not Related (NOT RELATED)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:29:39

US3662116
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:24:58
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:00:12
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Not Applicable (NOT APPLICABLE)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:29:39

US3662116
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:24:58
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:00:12
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:29:39

US3662116
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:24:58
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:00:12
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '1'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:29:39

US3662116
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:24:58
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:00:12
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:29:39

US3662116
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:24:58
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:00:12
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:29:39

US3662116
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:24:58
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:00:12
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:29:39

US3662116
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:24:58
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:37
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:00:12
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:29:39

US3662116
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:24:58
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:37
User entered '0'	System	22 Feb 2021 16:29:39

US3662116
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:24:58
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:37
User entered '1'	System	22 Feb 2021 16:29:39

US3662116
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 09:24:58
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:37

FDA-CBER-2022-1614-2920190

US3662116
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:24:58
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:42

FDA-CBER-2022-1614-2920191

US3662116
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:24:58
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:42
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 13:02:02
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' answered with 'subject was assessed for potential COVID-19 infection.' (Site from DM).	Angela Snyder (b) (4) (b) (4)	30 Mar 2021 13:55:52
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 13:59:39
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:04:52
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Sinusitis, LLT: Sinusitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:24:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:24:53
Data point term sent to Coder	System	18 Mar 2021 22:08:34
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Sinusitis, LLT: Sinusitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Feb 2021 16:31:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Feb 2021 16:31:59
Data point term sent to Coder	System	22 Feb 2021 16:31:06
User entered 'sinusitis'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:30:49

US3662116
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:24:58
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:04:52
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:30:49

US3662116
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:24:58
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:04:52
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:30:49

US3662116
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:24:58
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:04:52
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:30:49

US3662116
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:24:58
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:04:52
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '14 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:30:49

US3662116
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:24:58
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:04:52
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:30:49

US3662116
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:24:58
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:42
User entered empty.	System	22 Feb 2021 16:30:49

US3662116
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:24:58
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:04:52
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:30:49

US3662116
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:24:58
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:04:52
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '16 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:30:49

US3662116
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:24:58
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:04:52
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:30:49

US3662116
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:24:58
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:42
User entered empty.	System	22 Feb 2021 16:30:49

US3662116
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:24:58
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:04:52
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:30:49

US3662116
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:24:58
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:04:52
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:30:49

US3662116
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:24:58
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:04:52
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:30:49

US3662116
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:24:58
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:04:52
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:30:49

US3662116
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:24:58
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:04:52
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:30:49

US3662116
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:24:58
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:04:52
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:30:49

US3662116
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:24:58
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:04:52
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:30:49

FDA-CBER-2022-1614-2920209

US3662116
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:24:58
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:04:52
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:30:49

US3662116
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:24:58
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:04:52
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:30:49

US3662116
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:24:58
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:04:52
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:30:49

US3662116
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:24:58
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:04:52
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:30:49

US3662116
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:24:58
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:04:52
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:30:49

US3662116
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:24:58
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:04:52
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Not Related (NOT RELATED)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:30:49

US3662116
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:24:58
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:04:52
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Not Related (NOT RELATED)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:30:49

US3662116
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:24:58
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:04:52
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Not Applicable (NOT APPLICABLE)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:30:49

US3662116
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:24:58
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:04:52
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:30:49

US3662116
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:24:58
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:04:52
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '1'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:30:49

US3662116
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:24:58
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:04:52
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:30:49

US3662116
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:24:58
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:04:52
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:30:49

US3662116
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:24:58
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:04:52
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:30:49

US3662116
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:24:58
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:42
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:04:52
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:30:49

US3662116
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:24:58
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:42
User entered '0'	System	22 Feb 2021 16:30:49

US3662116
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:24:58
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:42
User entered '1'	System	22 Feb 2021 16:30:49

FDA-CBER-2022-1614-2920225

US3662116
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 09:24:58
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:42

FDA-CBER-2022-1614-2920226

US3662116
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 10 Jun 2021 09:24:58
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:47

FDA-CBER-2022-1614-2920227

US3662116
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 10 Jun 2021 09:24:58
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:47
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:05:46
User coded data point as SOC: Psychiatric disorders, HLGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:09:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:09:36
Data point term sent to Coder	System	18 Mar 2021 22:08:35
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User coded data point as SOC: Psychiatric disorders, HLGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Feb 2021 16:32:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Feb 2021 16:32:59
Data point term sent to Coder	System	22 Feb 2021 16:32:07
User entered 'insomnia'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:31:45

US3662116
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 10 Jun 2021 09:24:58
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:47
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:05:46
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:31:45

US3662116
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 10 Jun 2021 09:24:58
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:47
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:05:46
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:31:45

US3662116
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 10 Jun 2021 09:24:58
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:47
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:05:46
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:31:45

US3662116
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 10 Jun 2021 09:24:58
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:47
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:05:46
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '14 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:31:45

US3662116
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 10 Jun 2021 09:24:58
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:47
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:05:46
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:31:45

US3662116
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 10 Jun 2021 09:24:58
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:47
User entered empty.	System	22 Feb 2021 16:31:45

US3662116
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 10 Jun 2021 09:24:58
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:47
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:05:46
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:31:45

US3662116
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 10 Jun 2021 09:24:58
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:47
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:05:46
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '15 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:31:45

US3662116
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 10 Jun 2021 09:24:58
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:47
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:05:46
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:31:45

US3662116
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 10 Jun 2021 09:24:58
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:47
User entered empty.	System	22 Feb 2021 16:31:45

US3662116
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 10 Jun 2021 09:24:58
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:47
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:05:46
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:31:45

US3662116
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 10 Jun 2021 09:24:58
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:47
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:05:46
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:31:45

US3662116
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 10 Jun 2021 09:24:58
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:47
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:05:46
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:31:45

US3662116
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 10 Jun 2021 09:24:58
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:47
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:05:46
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:31:45

US3662116
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 10 Jun 2021 09:24:58
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:47
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:05:46
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:31:45

US3662116
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 10 Jun 2021 09:24:58
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:47
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:05:46
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:31:45

FDA-CBER-2022-1614-2920244

US3662116
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 10 Jun 2021 09:24:58
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:47
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:05:46
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:31:45

US3662116
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 10 Jun 2021 09:24:58
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:47
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:05:46
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:31:45

US3662116
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 10 Jun 2021 09:24:58
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:47
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:05:46
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:31:45

US3662116
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 10 Jun 2021 09:24:58
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:47
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:05:46
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:31:45

US3662116
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 10 Jun 2021 09:24:58
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:47
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:05:46
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:31:45

US3662116
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 10 Jun 2021 09:24:58
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:47
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:05:46
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:31:45

US3662116
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 10 Jun 2021 09:24:58
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:47
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:05:46
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Not Related (NOT RELATED)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:31:45

US3662116
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 10 Jun 2021 09:24:58
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:47
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:05:46
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Not Related (NOT RELATED)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:31:45

US3662116
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 10 Jun 2021 09:24:58
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:47
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:05:46
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Not Applicable (NOT APPLICABLE)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:31:45

US3662116
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 10 Jun 2021 09:24:58
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:47
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:05:46
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:31:45

US3662116
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 10 Jun 2021 09:24:58
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:47
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:05:46
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '1'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:31:45

US3662116
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 10 Jun 2021 09:24:58
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:47
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:05:46
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:31:45

FDA-CBER-2022-1614-2920256

US3662116
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 10 Jun 2021 09:24:58
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:47
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:05:46
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:31:45

US3662116
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 10 Jun 2021 09:24:58
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:47
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:05:46
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:31:45

US3662116
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 10 Jun 2021 09:24:58
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:47
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:05:46
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:31:45

US3662116
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 10 Jun 2021 09:24:58
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:47
User entered '0'	System	22 Feb 2021 16:31:45

US3662116
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 10 Jun 2021 09:24:58
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:47
User entered '1'	System	22 Feb 2021 16:31:45

US3662116
Folder: Adverse Events
Form: Adverse Events (6)
Generated On: 10 Jun 2021 09:24:58
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:47

US3662116
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 10 Jun 2021 09:24:58
Adverse event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:09:02
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:24:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:24:53
Data point term sent to Coder	System	18 Mar 2021 22:08:35
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Mar 2021 20:40:56
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Mar 2021 20:40:56
Data point term sent to Coder	System	22 Feb 2021 16:33:09
User entered 'nausea, intermittent post small bowel obstruction'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:32:43

US3662116
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 10 Jun 2021 09:24:58
Was this a medically-attended AE?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:09:02
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:32:43

US3662116
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 10 Jun 2021 09:24:58
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:09:02
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:32:43

US3662116
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 10 Jun 2021 09:24:58
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:09:02
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:32:43

US3662116
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 10 Jun 2021 09:24:58
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:09:02
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '16 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:32:43

US3662116
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 10 Jun 2021 09:24:58
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:09:02
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:32:43

US3662116
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 10 Jun 2021 09:24:58
AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	22 Feb 2021 16:32:43

US3662116
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 10 Jun 2021 09:24:58
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:09:02
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:32:43

US3662116
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 10 Jun 2021 09:24:58
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:09:02
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:32:43

US3662116
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 10 Jun 2021 09:24:58
End time *(00:00-23:59)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:09:02
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:32:43

US3662116
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 10 Jun 2021 09:24:58
AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	22 Feb 2021 16:32:43

US3662116
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 10 Jun 2021 09:24:58
Severity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:09:02
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:32:43

US3662116
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 10 Jun 2021 09:24:58
Is the adverse event serious?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:09:02
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:32:43

US3662116
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 10 Jun 2021 09:24:58
Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:09:02
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:32:43

US3662116
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 10 Jun 2021 09:24:58
Life threatening

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:09:02
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:32:43

US3662116
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 10 Jun 2021 09:24:58
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:09:02
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:32:43

US3662116
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 10 Jun 2021 09:24:58
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:09:02
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:32:43

US3662116
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 10 Jun 2021 09:24:58
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:09:02
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:32:43

US3662116
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 10 Jun 2021 09:24:58
Admitted to ICU?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:09:02
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:32:43

US3662116
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 10 Jun 2021 09:24:58
Number of Days in ICU

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:09:02
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:32:43

US3662116
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 10 Jun 2021 09:24:58
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:09:02
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:32:43

US3662116
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 10 Jun 2021 09:24:58
Congenital anomaly or birth defect

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:09:02
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:32:43

US3662116
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 10 Jun 2021 09:24:58
Other medically important event

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:09:02
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:32:43

US3662116
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 10 Jun 2021 09:24:58
Relationship to investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:09:02
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Not Related (NOT RELATED)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:32:43

US3662116
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 10 Jun 2021 09:24:58
Relationship to Study Procedure

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:09:02
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Not Related (NOT RELATED)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:32:43

US3662116
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 10 Jun 2021 09:24:58
Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:09:02
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Not Applicable (NOT APPLICABLE)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:32:43

US3662116
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 10 Jun 2021 09:24:58
None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:09:02
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:32:43

US3662116
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 10 Jun 2021 09:24:58
Concomitant Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:09:02
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '1'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:32:43

US3662116
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 10 Jun 2021 09:24:58
Concomitant Procedure

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:09:02
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:32:43

US3662116
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 10 Jun 2021 09:24:58
Outcome

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:09:02
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:32:43

US3662116
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 10 Jun 2021 09:24:58
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:09:02
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:32:43

US3662116
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 10 Jun 2021 09:24:58
Narrative

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 20:09:02
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:32:43

US3662116
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 10 Jun 2021 09:24:58
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '0'	System	22 Feb 2021 16:32:43

US3662116
Folder: Adverse Events
Form: Adverse Events (7)
Generated On: 10 Jun 2021 09:24:58
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	22 Feb 2021 16:32:43

US3662116
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 10 Jun 2021 09:24:58
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:16

FDA-CBER-2022-1614-2920297

US3662116
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 10 Jun 2021 09:24:58
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:16
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:07:26
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Electrolyte and fluid balance conditions, HLT: Potassium imbalance, PT: Hypokalaemia, LLT: Hypokalemia - version MedDRA\\23.0.	Coder Import (b) (4)	25 Mar 2021 18:57:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Mar 2021 18:57:29
Data point term sent to Coder	System	25 Mar 2021 18:56:35
User entered 'hypokalemia'	michelle saemann (b) (4)	25 Mar 2021 18:56:22

FDA-CBER-2022-1614-2920298

US3662116
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 10 Jun 2021 09:24:58
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:16
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:07:26
User entered 'Yes (Y)'	michelle saemann (b) (4)	25 Mar 2021 18:56:22

US3662116
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 10 Jun 2021 09:24:58
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:16
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:07:26
User entered 'No (N)'	michelle saemann (b) (4)	25 Mar 2021 18:56:22

FDA-CBER-2022-1614-2920300

US3662116
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 10 Jun 2021 09:24:58
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:16
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:07:26
User entered 'No (N)'	michelle saemann (b) (4)	25 Mar 2021 18:56:22

US3662116
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 10 Jun 2021 09:24:58
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:16
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:07:26
User entered '13 Feb 2021'	michelle saemann (b) (4) (b) (4)	25 Mar 2021 18:56:22

US3662116
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 10 Jun 2021 09:24:58
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:16
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:07:26
User entered empty.	michelle saemann (b) (4)	25 Mar 2021 18:56:22

US3662116
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 10 Jun 2021 09:24:58
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:16
User entered empty.	System	25 Mar 2021 18:56:22

US3662116
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 10 Jun 2021 09:24:58
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:16
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:07:26
User entered 'No (N)'	michelle saemann (b) (4)	25 Mar 2021 18:56:22

US3662116
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 10 Jun 2021 09:24:58
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:16
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:07:26
User entered '13 Feb 2021'	michelle saemann (b) (4)	25 Mar 2021 18:56:22

US3662116
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 10 Jun 2021 09:24:58
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:16
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:07:26
User entered empty.	michelle saemann (b) (4)	25 Mar 2021 18:56:22

US3662116
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 10 Jun 2021 09:24:58
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:16
User entered empty.	System	25 Mar 2021 18:56:22

US3662116
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 10 Jun 2021 09:24:58
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:16
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:07:26
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	michelle saemann (b) (4) (b) (4)	25 Mar 2021 18:56:22

US3662116
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 10 Jun 2021 09:24:58
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:16
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	05 Apr 2021 16:07:26
User entered 'No (N)'	michelle saemann (b) (4) (b) (4)	25 Mar 2021 18:56:22

US3662116
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 10 Jun 2021 09:24:58
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:16
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:07:26
User entered '0'	michelle saemann (b) (4) (b) (4)	25 Mar 2021 18:56:22

US3662116
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 10 Jun 2021 09:24:58
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:16
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:07:26
User entered '0'	michelle saemann (b) (4) (b) (4)	25 Mar 2021 18:56:22

US3662116
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 10 Jun 2021 09:24:58
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:16
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:07:26
User entered '0'	michelle saemann (b) (4)	25 Mar 2021 18:56:22

US3662116
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 10 Jun 2021 09:24:58
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:16
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:07:26
User entered empty.	michelle saemann (b) (4)	25 Mar 2021 18:56:22

FDA-CBER-2022-1614-2920314

US3662116
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 10 Jun 2021 09:24:58
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:16
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:07:26
User entered empty.	michelle saemann (b) (4) (b) (4)	25 Mar 2021 18:56:22

FDA-CBER-2022-1614-2920315

US3662116
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 10 Jun 2021 09:24:58
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:16
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:07:26
User entered empty.	michelle saemann (b) (4)	25 Mar 2021 18:56:22

US3662116
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 10 Jun 2021 09:24:58
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:16
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:07:26
User entered empty.	michelle saemann (b) (4)	25 Mar 2021 18:56:22

US3662116
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 10 Jun 2021 09:24:58
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:16
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:07:26
User entered '0'	michelle saemann (b) (4) (b) (4)	25 Mar 2021 18:56:22

US3662116
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 10 Jun 2021 09:24:58
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:16
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:07:26
User entered '0'	michelle saemann (b) (4)	25 Mar 2021 18:56:22

US3662116
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 10 Jun 2021 09:24:58
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:16
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:07:26
User entered '0'	michelle saemann (b) (4)	25 Mar 2021 18:56:22

US3662116
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 10 Jun 2021 09:24:58
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:16
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:07:26
User entered 'Not Related (NOT RELATED)'	michelle saemann (b) (4)	25 Mar 2021 18:56:22

US3662116
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 10 Jun 2021 09:24:58
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:16
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:07:26
User entered 'Not Related (NOT RELATED)'	michelle saemann (b) (4)	25 Mar 2021 18:56:22

US3662116
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 10 Jun 2021 09:24:58
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:16
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:07:26
User entered 'Not Applicable (NOT APPLICABLE)'	michelle saemann (b) (4) (b) (4)	25 Mar 2021 18:56:22

US3662116
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 10 Jun 2021 09:24:58
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:16
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:07:26
User entered '0'	michelle saemann (b) (4)	25 Mar 2021 18:56:22

US3662116
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 10 Jun 2021 09:24:58
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:16
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:07:26
User entered '1'	michelle saemann (b) (4)	25 Mar 2021 18:56:22

US3662116
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 10 Jun 2021 09:24:58
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:16
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:07:26
User entered '0'	michelle saemann (b) (4) (b) (4)	25 Mar 2021 18:56:22

US3662116
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 10 Jun 2021 09:24:58
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:16
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 16:07:26
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	michelle saemann (b) (4) (b) (4)	25 Mar 2021 18:56:22

US3662116
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 10 Jun 2021 09:24:58
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:16
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:07:26
User entered empty.	michelle saemann (b) (4)	25 Mar 2021 18:56:22

US3662116
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 10 Jun 2021 09:24:58
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:16
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:07:26
User entered empty.	michelle saemann (b) (4)	25 Mar 2021 18:56:22

US3662116
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 10 Jun 2021 09:24:58
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:16
User entered '0'	System	25 Mar 2021 18:56:22

US3662116
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 10 Jun 2021 09:24:58
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:16
User entered '1'	System	25 Mar 2021 18:56:22

US3662116
Folder: Adverse Events
Form: Adverse Events (8)
Generated On: 10 Jun 2021 09:24:58
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:12:16

FDA-CBER-2022-1614-2920332

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Generated On: 10 Jun 2021 09:24:58
Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:26:54
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User closed query 'Per DM CLR: Per Diary Dose 2 Day 2-3, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 03:49:28
Query 'Per DM CLR: Per Diary Dose 2 Day 2-3, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' answered with 'Participant did not report taking any meds for HA, only for arm pain and fever. ' (Site from DM).	michelle saemann (b) (4) (b) (4)	17 Feb 2021 16:01:43
User opened query 'Per DM CLR: Per Diary Dose 2 Day 2-3, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 13:18:07
Query 'Per DM CLR: Per Diary Dose 2 Day 2-3, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' canceled (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 04:19:53

US3662116

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:24:58

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Per Diary Dose 2 Day 2-3, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 14:03:57
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:38:20
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:12:21

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:24:58
Name of Medication

Audit	User	Time (GMT)
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 BESILATE, PRODUCTSYNONYM: AMLODIPINE BESYLATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:24:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:24:52
Data point term sent to Coder	System	18 Mar 2021 22:08:35
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:38:45
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 BESILATE, PRODUCTSYNONYM: AMLODIPINE BESYLATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 14:14:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 14:14:50
Data point term sent to Coder	System	22 Sep 2020 14:14:09
User entered 'AMLODIPINE BESYLATE'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:13:25

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:24:58
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:38:45
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:13:25

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:24:58
Indication

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:38:45
User entered 'HYPERTENSION'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:13:25

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:24:58
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:38:45
User entered '10'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:13:25

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:24:58
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:38:45
User entered 'mg (mg)'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:13:25

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:24:58
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:38:45
User entered empty.	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:13:25

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:24:58
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:38:45
User entered 'once daily (QD)'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:13:25

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:24:58
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:38:45
User entered empty.	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:13:25

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:24:58
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:38:45
User entered 'Oral (ORAL)'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:13:25

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:24:58
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:38:45
User entered empty.	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:13:25

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:24:58
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:38:45
User entered '01 Jul 2001'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:13:25

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:24:58
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:38:45
User entered '0'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:13:25

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:24:58
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:38:45
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:13:25

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:24:58
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:38:45
User entered empty.	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:13:25

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:24:58
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:38:45
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:13:25

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:24:58
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 14:13:25

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 14:13:25

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Sep 2020 14:13:25

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:24:58
Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:09:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:09:56
Data point term sent to Coder	System	18 Mar 2021 22:08:35
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:38:45
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 14:14:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 14:14:50
Data point term sent to Coder	System	22 Sep 2020 14:14:10
User entered 'LISINOPRIL'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:14:08

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:24:58
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:38:45
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:14:08

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:24:58
Indication

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:38:45
User entered 'HYPERTENSION'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:14:08

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:24:58
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:09:56
DataPoint Un-verified.	michelle saemann (b) (4) (b) (4)	06 Apr 2021 13:17:19
Signature has been broken.	michelle saemann (b) (4) (b) (4)	06 Apr 2021 13:17:19
User entered '20' reason for change: Data Entry Error	michelle saemann (b) (4) (b) (4)	06 Apr 2021 13:17:19
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:38:45
User entered '25'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:14:08

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:24:58
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:38:45
User entered 'mg (mg)'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:14:08

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:24:58
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:38:45
User entered empty.	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:14:08

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:24:58
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:38:45
User entered 'once daily (QD)'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:14:08

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:24:58
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:38:45
User entered empty.	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:14:08

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:24:58
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:38:45
User entered 'Oral (ORAL)'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:14:08

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:24:58
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:38:45
User entered empty.	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:14:08

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:24:58
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:38:45
User entered '01 Jul 2001'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:14:08

FDA-CBER-2022-1614-2920363

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:24:58
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:38:45
User entered '0'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:14:08

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:24:58
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:38:45
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:14:08

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:24:58
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:38:45
User entered empty.	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:14:08

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:24:58
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 13:38:45
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:14:08

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:24:58
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 14:14:08

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 14:14:08

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Sep 2020 14:14:08

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:24:58
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:46:59
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)	18 Mar 2021 22:09:54
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 Mar 2021 22:09:54
Data point term sent to Coder	System	18 Mar 2021 22:08:35
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:50:42
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)	26 Oct 2020 13:38:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 13:38:31
Data point term sent to Coder	System	26 Oct 2020 13:37:32
User entered 'TYLENOL'	Brenda Miller (b) (4) (b) (4)	26 Oct 2020 13:36:33

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:24:58
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:46:59
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:50:42
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	26 Oct 2020 13:36:33

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:24:58
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:46:59
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the ARM PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of ARM PAIN did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 04:50:29
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the ARM PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of ARM PAIN did not meet the AE reporting criteria. ' answered with 'Does not meet the criteria for AE or MAAE. ' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 20:51:26

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:24:58
Indication

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the ARM PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of ARM PAIN did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 11:12:50
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:50:42
User entered 'ARM PAIN/FEVER'	Brenda Miller (b) (4) (b) (4)	26 Oct 2020 13:36:33

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:24:58
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:46:59
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:50:42
User entered '1000'	Brenda Miller (b) (4) (b) (4)	26 Oct 2020 13:36:33

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:24:58
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:46:59
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:50:42
User entered 'mg (mg)'	Brenda Miller (b) (4) (b) (4)	26 Oct 2020 13:36:33

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:24:58
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:46:59
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:50:42
User entered empty.	Brenda Miller (b) (4) (b) (4)	26 Oct 2020 13:36:33

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:24:58
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:46:59
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:50:42
User entered 'as needed (PRN)'	Brenda Miller (b) (4) (b) (4)	26 Oct 2020 13:36:33

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:24:58
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:46:59
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:50:42
User entered empty.	Brenda Miller (b) (4) (b) (4)	26 Oct 2020 13:36:33

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:24:58
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:46:59
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:50:42
User entered 'Oral (ORAL)'	Brenda Miller (b) (4) (b) (4)	26 Oct 2020 13:36:33

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:24:58
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:46:59
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:50:42
User entered empty.	Brenda Miller (b) (4) (b) (4)	26 Oct 2020 13:36:33

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:24:58
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:46:59
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:50:42
User entered '17 Oct 2020'	Brenda Miller (b) (4) (b) (4)	26 Oct 2020 13:36:33

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:24:58
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:46:59
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:50:42
User entered '0'	Brenda Miller (b) (4) (b) (4)	26 Oct 2020 13:36:33

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:24:58
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:46:59
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:50:42
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	26 Oct 2020 13:36:33

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:24:58
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:46:59
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:50:42
User entered '17 Oct 2020'	Brenda Miller (b) (4) (b) (4)	26 Oct 2020 13:36:33

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:24:58
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:46:59
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:13:28
User entered 'Yes (Y)' reason for change: Data Entry Error	Angela Snyder (b) (4)	15 Jan 2021 12:29:03
DataPoint Un-verified.	(b) (4), (b) (6)	14 Jan 2021 20:33:10
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 20:33:03
User closed query 'Per CDM: Requery: Response noted, however please confirm if this should be considered as Unsolicited event and update accordingly in AE eCRF.Thank you' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 04:55:34
Query 'Per CDM: Requery: Response noted, however please confirm if this should be considered as Unsolicited event and update accordingly in AE eCRF.Thank you' answered with 'Data updated' (Site from DM).	Angela Snyder (b) (4)	31 Dec 2020 14:05:40
DataPoint Un-verified.	Angela Snyder (b) (4)	31 Dec 2020 14:05:30
User entered 'No (N)' reason for change: Data Entry Error	Angela Snyder (b) (4)	31 Dec 2020 14:05:30
User opened query 'Per CDM: Requery: Response noted, however please confirm if this should be considered as Unsolicited event and update accordingly in AE eCRF.Thank you' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 10:18:22
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of FEVER in eDiary. Please note that this CM was given at Day 2 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRF, Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 10:05:43

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:24:58
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of FEVER in eDiary. Please note that this CM was given at Day 2 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRF, Update as appropriate. ' answered with 'Participant recorded temp. of 99.2 F. She considered this a fever and said she took Tylenol for fever. No AE added.' (Site from DM).	Angela Snyder (b) (4) (b) (4)	23 Dec 2020 14:02:20
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of FEVER in eDiary. Please note that this CM was given at Day 2 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRF, Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 11:13:01
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:50:42
User entered 'Yes (Y)'	Brenda Miller (b) (4) (b) (4)	26 Oct 2020 13:36:33

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:24:58
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:46:59
User entered empty.	System	26 Oct 2020 13:36:33

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:46:59
User entered empty.	System	26 Oct 2020 13:36:33

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:46:59
User entered empty.	System	26 Oct 2020 13:36:33

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:24:58
Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:09:30
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 Mar 2021 22:09:30
Data point term sent to Coder	System	18 Mar 2021 22:08:37
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 20:33:03
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 19:20:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 19:20:50
Data point term sent to Coder	System	11 Dec 2020 19:20:05
User entered 'METFORMIN'	Angela Snyder (b) (4) (b) (4)	11 Dec 2020 19:19:43

FDA-CBER-2022-1614-2920391

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:24:58
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 20:33:03
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	11 Dec 2020 19:19:43

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:24:58
Indication

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 20:33:03
User entered 'PRE-DIABETIC'	Angela Snyder (b) (4) (b) (4)	11 Dec 2020 19:19:43

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:24:58
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 20:33:03
User entered '500'	Angela Snyder (b) (4) (b) (4)	11 Dec 2020 19:19:43

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:24:58
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:15:28
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 11:46:27
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'UPDATED. ' (Site from DM).	MaKayla Bishop (b) (4) (b) (4)	22 Feb 2021 14:32:01
User entered 'mg (mg)' reason for change: Data Entry Error	MaKayla Bishop (b) (4) (b) (4)	22 Feb 2021 14:31:54
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 09:37:36
DataPoint Un-verified.	(b) (4), (b) (6)	14 Jan 2021 20:33:06
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 20:33:03
User entered 'mL (mL)'	Angela Snyder (b) (4) (b) (4)	11 Dec 2020 19:19:43

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:24:58
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 20:33:03
User entered empty.	Angela Snyder (b) (4) (b) (4)	11 Dec 2020 19:19:43

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:24:58
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 20:33:03
User entered 'twice daily (BID)'	Angela Snyder (b) (4) (b) (4)	11 Dec 2020 19:19:43

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:24:58
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 20:33:03
User entered empty.	Angela Snyder (b) (4) (b) (4)	11 Dec 2020 19:19:43

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:24:58
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 20:33:03
User entered 'Oral (ORAL)'	Angela Snyder (b) (4) (b) (4)	11 Dec 2020 19:19:43

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:24:58
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 20:33:03
User entered empty.	Angela Snyder (b) (4) (b) (4)	11 Dec 2020 19:19:43

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:24:58
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 20:33:03
User entered '16 Nov 2020'	Angela Snyder (b) (4) (b) (4)	11 Dec 2020 19:19:43

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:24:58
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 20:33:03
User entered '0'	Angela Snyder (b) (4) (b) (4)	11 Dec 2020 19:19:43

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:24:58
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 20:33:03
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	11 Dec 2020 19:19:43

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:24:58
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 20:33:03
User entered empty.	Angela Snyder (b) (4) (b) (4)	11 Dec 2020 19:19:43

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:24:58
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 20:33:03
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	11 Dec 2020 19:19:43

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:24:58
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	11 Dec 2020 19:19:43

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	11 Dec 2020 19:19:43

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Dec 2020 19:19:43

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:24:58
Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:37:48
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: CODEINE PHOSPHATE;PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN;CODEINE PHOSPHATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:09:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:09:57
Data point term sent to Coder	System	18 Mar 2021 22:08:36
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: CODEINE PHOSPHATE;PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN;CODEINE PHOSPHATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 17:05:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 17:05:59
Data point term sent to Coder	System	22 Feb 2021 16:36:15
User entered 'acetaminophen ; comb; codeine phosphate'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:35:42

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:24:58
Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:37:48
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:35:42

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:24:58
Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:37:48
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User closed query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 04:55:46
Query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.' answered with 'MH updated' (Site from DM).	Angela Snyder (b) (4) (b) (4)	15 Mar 2021 12:56:42
User opened query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 12:29:05
User entered 'generalized pain'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:35:42

FDA-CBER-2022-1614-2920411

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:24:58
Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:37:48
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '300/30'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:35:42

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:24:58
Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:37:48
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'mg (mg)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:35:42

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:24:58
If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:37:48
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:35:42

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:24:58
Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:37:48
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'other (OTHER)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:35:42

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:24:58
If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 15:57:16
User closed query 'Per source is Q6 please verify and update. ' (Site from CRA).	(b) (4), (b) (6)	05 Apr 2021 14:55:58
Query 'Per source is Q6 please verify and update. ' answered with 'Visit notes states q 4-6 hours, which is how participant states she is taking it. ' (Site from CRA).	michelle saemann (b) (4) (b) (4)	25 Mar 2021 19:07:01
DataPoint Un-verified.	(b) (4), (b) (6)	24 Mar 2021 18:37:59
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:37:48
User opened query 'Per source is Q6 please verify and update. ' (Site from CRA).	(b) (4), (b) (6)	24 Mar 2021 18:34:03
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'every four to 6 hours'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:35:42

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:24:58
Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:37:48
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Oral (ORAL)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:35:42

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:24:58
If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:37:48
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:35:42

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:24:58
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:37:48
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '1 Nov 2019'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:35:42

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:24:58
Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:37:48
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:35:42

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:24:58
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:37:48
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:35:42

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:24:58
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:37:48
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:35:42

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:24:58
Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:37:48
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:35:42

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:24:58
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	22 Feb 2021 16:35:42

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	22 Feb 2021 16:35:42

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	22 Feb 2021 16:35:42

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:24:58
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:33:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:37:52
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:09:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:09:52
Data point term sent to Coder	System	18 Mar 2021 22:08:36
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 16:39:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 16:39:00
Data point term sent to Coder	System	22 Feb 2021 16:38:18
User entered 'hydrochlorothiazide'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:37:38

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:24:58
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:33:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:37:52
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:37:38

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:24:58
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:33:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:37:52
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'htn'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:37:38

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:24:58
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:33:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:37:52
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '25'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:37:38

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:24:58
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:33:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:37:52
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'mg (mg)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:37:38

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:24:58
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:33:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:37:52
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:37:38

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:24:58
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:33:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:37:52
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'once daily (QD)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:37:38

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:24:58
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:33:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:37:52
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:37:38

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:24:58
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:33:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:37:52
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Oral (ORAL)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:37:38

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:24:58
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:33:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:37:52
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:37:38

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:24:58
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:33:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:37:52
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '7 Jul 2020'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:37:38

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:24:58
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:33:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:37:52
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:37:38

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:24:58
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:33:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:37:52
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)' reason for change: Data Entry Error	Angela Snyder (b) (4) (b) (4)	08 Mar 2021 15:15:09
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:37:38

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:24:58
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:33:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:37:52
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '4 Mar 2021' reason for change: Data Entry Error	Angela Snyder (b) (4) (b) (4)	08 Mar 2021 15:15:09
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:37:38

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:24:58
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:33:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:37:52
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:37:38

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:24:58
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:33:48
User entered '1'	System	22 Feb 2021 16:37:38

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:33:48
User entered '1'	System	22 Feb 2021 16:37:38

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:33:48
User entered '804 (804)'	System	22 Feb 2021 16:37:38

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:24:58
Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:55:24
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: ESOMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:09:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:09:52
Data point term sent to Coder	System	18 Mar 2021 22:08:37
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: ESOMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 22:01:06
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 22:01:06
Data point term sent to Coder	System	22 Feb 2021 16:39:20
User entered 'esomeprazole; nexium'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:38:37

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:24:58
Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:55:24
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:38:37

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:24:58
Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:55:24
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User closed query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 04:58:36
Query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF.' answered with 'MH updated' (Site from DM).	Angela Snyder (b) (4) (b) (4)	15 Mar 2021 12:56:54
User opened query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 12:29:15
User entered 'gerd'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:38:37

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:24:58
Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:55:24
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '20'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:38:37

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:24:58
Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:55:24
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'mg (mg)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:38:37

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:24:58
If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:55:24
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:38:37

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:24:58
Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:55:24
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'once daily (QD)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:38:37

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:24:58
If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:55:24
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:38:37

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:24:58
Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:55:24
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Oral (ORAL)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:38:37

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:24:58
If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:55:24
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:38:37

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:24:58
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:55:24
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '7 Jul 2020'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:38:37

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:24:58
Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:55:24
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:38:37

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:24:58
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:55:24
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:38:37

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:24:58
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:55:24
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:38:37

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:24:58
Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:55:24
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:38:37

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:24:58
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	22 Feb 2021 16:38:37

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	22 Feb 2021 16:38:37

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Feb 2021 16:38:37

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:24:58
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:32:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:55:28
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)	18 Mar 2021 22:09:32
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 Mar 2021 22:09:32
Data point term sent to Coder	System	18 Mar 2021 22:08:36
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
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)	22 Feb 2021 16:40:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 16:40:59
Data point term sent to Coder	System	22 Feb 2021 16:40:20
User entered 'Tylenol'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:39:41

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:24:58
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:32:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:55:28
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:39:41

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:24:58
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:32:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:55:28
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the ARM PAIN/FEVER is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of ARM PAIN/FEVER did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6) (b) (4)	17 Mar 2021 05:04:04
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the ARM PAIN/FEVER is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of ARM PAIN/FEVER did not meet the AE reporting criteria.' answered with 'solicited adverse reaction of ARM PAIN/FEVER did not meet the AE reporting criteria. ' (Site from DM).	Angela Snyder (b) (4) (b) (4)	15 Mar 2021 12:52:00

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:24:58
Indication

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the ARM PAIN/FEVER is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of ARM PAIN/FEVER did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 12:29:30
User entered 'arm pain/fever'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:39:41

FDA-CBER-2022-1614-2920466

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:24:58
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:32:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:55:28
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '1000'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:39:41

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:24:58
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:32:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:55:28
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'mg (mg)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:39:41

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:24:58
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:32:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:55:28
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:39:41

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:24:58
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:32:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:55:28
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'as needed (PRN)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:39:41

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:24:58
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:32:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:55:28
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:39:41

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:24:58
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:32:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:55:28
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Oral (ORAL)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:39:41

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:24:58
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:32:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:55:28
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:39:41

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:24:58
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:32:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:55:28
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '17 Oct 2020'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:39:41

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:24:58
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:32:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:55:28
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:39:41

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:24:58
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:32:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:55:28
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:39:41

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:24:58
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:32:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:55:28
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '17 Oct 2020'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:39:41

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:24:58
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:32:35
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:55:28
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:39:41

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:24:58
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:32:35
User entered empty.	System	22 Feb 2021 16:39:41

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:32:35
User entered empty.	System	22 Feb 2021 16:39:41

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:32:35
User entered empty.	System	22 Feb 2021 16:39:41

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:24:58
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:46:30
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:56:25
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:09:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:09:39
Data point term sent to Coder	System	18 Mar 2021 22:08:37
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 16:41:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 16:41:59
Data point term sent to Coder	System	22 Feb 2021 16:41:21
User entered 'zofran'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:41:03

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:24:58
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:46:30
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:56:25
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:41:03

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:24:58
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:46:30
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:56:25
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'small bowel obstruction'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:41:03

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:24:58
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:46:30
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:56:25
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '8'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:41:03

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:24:58
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:46:30
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:56:25
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'mg (mg)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:41:03

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:24:58
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:46:30
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:56:25
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:41:03

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:24:58
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:46:30
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:56:25
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'once (ONCE)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:41:03

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:24:58
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:46:30
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:56:25
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:41:03

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:24:58
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:46:30
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:56:25
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Intravenous (INTRAVENOUS)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:41:03

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:24:58
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:46:30
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:56:25
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:41:03

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:24:58
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:46:30
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:56:25
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '11 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:41:03

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:24:58
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:46:30
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:56:25
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:41:03

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:24:58
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:46:30
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:56:25
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:41:03

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:24:58
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:46:30
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:56:25
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '11 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:41:03

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:24:58
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:46:30
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:56:25
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:41:03

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:24:58
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:46:30
User entered empty.	System	22 Feb 2021 16:41:03

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:46:30
User entered empty.	System	22 Feb 2021 16:41:03

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:46:30
User entered empty.	System	22 Feb 2021 16:41:03

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:24:58
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:38:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:56:31
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:09:38
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 Mar 2021 22:09:38
Data point term sent to Coder	System	18 Mar 2021 22:08:38
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 16:42:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 16:42:59
Data point term sent to Coder	System	22 Feb 2021 16:42:22
User entered 'zofran'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:41:59

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:24:58
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:38:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:56:31
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:41:59

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:24:58
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:38:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:56:31
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'small bowel obstruction'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:41:59

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:24:58
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:38:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:56:31
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '4'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:41:59

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:24:58
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:38:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:56:31
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'mg (mg)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:41:59

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:24:58
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:38:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:56:31
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:41:59

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:24:58
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:38:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:56:31
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'as needed (PRN)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:41:59

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:24:58
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:38:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:56:31
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:41:59

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:24:58
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:38:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:56:31
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Intravenous (INTRAVENOUS)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:41:59

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:24:58
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:38:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:56:31
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:41:59

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:24:58
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:38:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:56:31
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '11 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:41:59

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:24:58
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:38:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:56:31
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:41:59

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:24:58
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:38:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:56:31
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:41:59

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:24:58
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:38:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:56:31
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '16 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:41:59

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:24:58
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:38:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:56:31
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:41:59

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:24:58
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:38:53
User entered empty.	System	22 Feb 2021 16:41:59

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:38:53
User entered empty.	System	22 Feb 2021 16:41:59

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:38:53
User entered empty.	System	22 Feb 2021 16:41:59

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:24:58
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:46:04
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:33:11
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE SODIUM SESQUIHYDRATE, PRODUCTSYNONYM: PROTONIX [PANTOPRAZOLE SODIUM SESQUIHYDRATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:09:35
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 Mar 2021 22:09:35
Data point term sent to Coder	System	18 Mar 2021 22:08:37
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE SODIUM SESQUIHYDRATE, PRODUCTSYNONYM: PROTONIX [PANTOPRAZOLE SODIUM SESQUIHYDRATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 07:21:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 07:21:08
Data point term sent to Coder	System	22 Feb 2021 16:43:23
User entered 'pantoprazole ; protonix'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:43:00

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:24:58
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:46:04
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:33:11
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:43:00

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:24:58
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:46:04
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:33:11
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'small bowel obstruction'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:43:00

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:24:58
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:46:04
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:33:11
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '40'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:43:00

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:24:58
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:46:04
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:33:11
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'mg (mg)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:43:00

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:24:58
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:46:04
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:33:11
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:43:00

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:24:58
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:46:04
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:33:11
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'once daily (QD)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:43:00

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:24:58
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:46:04
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:33:11
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:43:00

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:24:58
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:46:04
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:33:11
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Intravenous (INTRAVENOUS)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:43:00

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:24:58
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:46:04
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:33:11
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:43:00

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:24:58
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:46:04
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:33:11
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '11 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:43:00

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:24:58
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:46:04
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:33:11
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:43:00

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:24:58
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:46:04
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:33:11
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:43:00

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:24:58
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:46:04
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:33:11
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '14 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:43:00

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:24:58
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:46:04
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:33:11
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:43:00

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:24:58
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:46:04
User entered '1'	System	22 Feb 2021 16:43:00

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:46:04
User entered '1'	System	22 Feb 2021 16:43:00

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:46:04
User entered '804 (804)'	System	22 Feb 2021 16:43:00

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:24:58
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:39:22
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:08:34
User coded data point as ATC: VARIOUS, ATC: CONTRAST MEDIA, ATC: X-RAY CONTRAST MEDIA, IODINATED, ATC: WATERSOLUBLE, NEPHROTROPIC, LOW OSMOLAR X-RAY CONTRAST MEDIA, PRODUCT: IOHEXOL, PRODUCTSYNONYM: OMNIPAQUE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:10:13
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 Mar 2021 22:10:13
Data point term sent to Coder	System	18 Mar 2021 22:08:38
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User coded data point as ATC: VARIOUS, ATC: CONTRAST MEDIA, ATC: X-RAY CONTRAST MEDIA, IODINATED, ATC: WATERSOLUBLE, NEPHROTROPIC, LOW OSMOLAR X-RAY CONTRAST MEDIA, PRODUCT: IOHEXOL, PRODUCTSYNONYM: OMNIPAQUE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 11:36:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 11:36:39
Data point term sent to Coder	System	22 Feb 2021 16:45:26
User entered 'omnipaque ; see iohexol'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:44:40

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:24:58
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:39:22
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:08:34
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:44:40

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:24:58
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:39:22
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:08:34
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'small bowel obstruction'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:44:40

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:24:58
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:39:22
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:08:34
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '150'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:44:40

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:24:58
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:39:22
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:08:34
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'mL (mL)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:44:40

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:24:58
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:39:22
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:08:34
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:44:40

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:24:58
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:39:22
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:08:34
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'once (ONCE)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:44:40

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:24:58
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:39:22
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:08:34
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:44:40

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:24:58
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:39:22
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:08:34
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Intravenous (INTRAVENOUS)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:44:40

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:24:58
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:39:22
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:08:34
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:44:40

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:24:58
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:39:22
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:08:34
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '11 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:44:40

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:24:58
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:39:22
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:08:34
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:44:40

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:24:58
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:39:22
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:08:34
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:44:40

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:24:58
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:39:22
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:08:34
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '11 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:44:40

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:24:58
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:39:22
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:08:34
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:44:40

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:24:58
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:39:22
User entered empty.	System	22 Feb 2021 16:44:40

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:39:22
User entered empty.	System	22 Feb 2021 16:44:40

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:39:22
User entered empty.	System	22 Feb 2021 16:44:40

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:24:58
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:39:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:09:13
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 Mar 2021 22:09:30
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 Mar 2021 22:09:30
Data point term sent to Coder	System	18 Mar 2021 22:08:38
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
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)	22 Feb 2021 16:45:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 16:45:59
Data point term sent to Coder	System	22 Feb 2021 16:45:25
User entered 'morphine'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:45:24

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:24:58
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:39:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:09:13
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:45:24

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:24:58
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:39:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:09:13
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'small bowel obstruction'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:45:24

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:24:58
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:39:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:09:13
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '4'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:45:24

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:24:58
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:39:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:09:13
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'mg (mg)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:45:24

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:24:58
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:39:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:09:13
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:45:24

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:24:58
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:39:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:09:13
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'once (ONCE)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:45:24

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:24:58
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:39:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:09:13
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:45:24

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:24:58
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:39:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:09:13
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Intravenous (INTRAVENOUS)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:45:24

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:24:58
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:39:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:09:13
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:45:24

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:24:58
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:39:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:09:13
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '11 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:45:24

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:24:58
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:39:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:09:13
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:45:24

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:24:58
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:39:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:09:13
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:45:24

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:24:58
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:39:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:09:13
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '11 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:45:24

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:24:58
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:39:53
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:09:13
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:45:24

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:24:58
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:39:53
User entered empty.	System	22 Feb 2021 16:45:24

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:39:53
User entered empty.	System	22 Feb 2021 16:45:24

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:39:53
User entered empty.	System	22 Feb 2021 16:45:24

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:24:58
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:40:20
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:32:11
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:09:51
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 Mar 2021 22:09:51
Data point term sent to Coder	System	18 Mar 2021 22:08:38
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 06:53:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 06:53:07
Data point term sent to Coder	System	22 Feb 2021 16:46:27
User entered 'methocarbamol'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:46:17

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:24:58
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:40:20
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:32:11
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:46:17

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:24:58
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:40:20
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:32:11
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'small bowel obstruction'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:46:17

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:24:58
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:40:20
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:32:11
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '1000'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:46:17

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:24:58
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:40:20
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:32:11
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'mg (mg)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:46:17

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:24:58
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:40:20
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:32:11
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:46:17

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:24:58
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:40:20
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:32:11
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'other (OTHER)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:46:17

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:24:58
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:40:20
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:32:11
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'every 8 hours'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:46:17

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:24:58
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:40:20
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:32:11
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Intravenous (INTRAVENOUS)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:46:17

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:24:58
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:40:20
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:32:11
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:46:17

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:24:58
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:40:20
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:32:11
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '11 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:46:17

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:24:58
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:40:20
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:32:11
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:46:17

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:24:58
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:40:20
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:32:11
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:46:17

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:24:58
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:40:20
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:32:11
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '14 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:46:17

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:24:58
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:40:20
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:32:11
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:46:17

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:24:58
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:40:20
User entered empty.	System	22 Feb 2021 16:46:17

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:40:20
User entered empty.	System	22 Feb 2021 16:46:17

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:40:20
User entered empty.	System	22 Feb 2021 16:46:17

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:24:58
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:40:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:10:29
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE HYDROCHLORIDE, PRODUCTSYNONYM: LIDOCAINE VISCOUS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:09:31
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 Mar 2021 22:09:31
Data point term sent to Coder	System	18 Mar 2021 22:08:38
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE HYDROCHLORIDE, PRODUCTSYNONYM: LIDOCAINE VISCOUS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 08:54:35
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 Mar 2021 08:54:35
Data point term sent to Coder	System	22 Feb 2021 16:48:29
User entered 'lidocaine hcl 2% viscous solution'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:47:44

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:24:58
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:40:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:10:29
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:47:44

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:24:58
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:40:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:10:29
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'sore throat due to ng tube placement'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:47:44

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:24:58
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:40:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:10:29
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '15'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:47:44

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:24:58
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:40:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:10:29
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'mL (mL)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:47:44

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:24:58
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:40:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:10:29
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:47:44

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:24:58
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:40:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:10:29
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'as needed (PRN)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:47:44

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:24:58
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:40:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:10:29
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:47:44

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:24:58
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:40:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:10:29
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Topical (TOPICAL)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:47:44

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:24:58
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:40:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:10:29
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:47:44

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:24:58
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:40:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:10:29
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '11 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:47:44

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:24:58
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:40:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:10:29
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:47:44

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:24:58
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:40:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:10:29
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:47:44

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:24:58
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:40:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:10:29
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '12 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:47:44

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:24:58
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:40:46
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:10:29
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:47:44

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:24:58
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:40:46
User entered empty.	System	22 Feb 2021 16:47:44

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:40:46
User entered empty.	System	22 Feb 2021 16:47:44

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:40:46
User entered empty.	System	22 Feb 2021 16:47:44

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:24:58
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:41:14
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:11:33
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGERS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:09:31
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 Mar 2021 22:09:31
Data point term sent to Coder	System	18 Mar 2021 22:08:38
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGERS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 17:05:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 17:05:00
Data point term sent to Coder	System	22 Feb 2021 16:49:30
User entered 'lactated ringers'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:48:56

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:24:58
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:41:14
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:11:33
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:48:56

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:24:58
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:41:14
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:11:33
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'small bowel obstruction'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:48:56

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:24:58
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:41:14
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:11:33
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '125'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:48:56

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:24:58
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:41:14
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:11:33
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'mL (mL)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:48:56

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:24:58
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:41:14
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:11:33
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:48:56

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:24:58
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:41:14
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:11:33
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'other (OTHER)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:48:56

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:24:58
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:41:14
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:11:33
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '125 ml / hour'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:48:56

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:24:58
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:41:14
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:11:33
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Intravenous (INTRAVENOUS)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:48:56

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:24:58
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:41:14
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:11:33
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:48:56

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:24:58
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:41:14
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:11:33
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '11 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:48:56

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:24:58
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:41:14
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:11:33
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:48:56

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:24:58
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:41:14
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:11:33
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:48:56

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:24:58
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:41:14
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:11:33
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '13 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:48:56

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:24:58
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:41:14
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:11:33
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:48:56

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:24:58
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:41:14
User entered empty.	System	22 Feb 2021 16:48:56

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:41:14
User entered empty.	System	22 Feb 2021 16:48:56

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:41:14
User entered empty.	System	22 Feb 2021 16:48:56

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:24:58
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:41:40
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:07
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE HYDROCHLORIDE, PRODUCTSYNONYM: HYDROMORPHONE HCL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:09:53
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 Mar 2021 22:09:53
Data point term sent to Coder	System	18 Mar 2021 22:08:38
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE HYDROCHLORIDE, PRODUCTSYNONYM: HYDROMORPHONE HCL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 16:51:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 16:51:00
Data point term sent to Coder	System	22 Feb 2021 16:50:31
User entered 'hydromorphone hcl'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:50:13

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:24:58
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:41:40
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:07
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:50:13

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:24:58
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:41:40
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:07
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'small bowel obstruction'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:50:13

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:24:58
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:41:40
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:07
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0.5'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:50:13

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:24:58
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:41:40
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:07
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'mL (mL)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:50:13

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:24:58
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:41:40
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:07
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:50:13

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:24:58
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:41:40
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:07
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'other (OTHER)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:50:13

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:24:58
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:41:40
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:07
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'every 4-6 hours'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:50:13

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:24:58
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:41:40
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:07
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Intravenous (INTRAVENOUS)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:50:13

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:24:58
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:41:40
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:07
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:50:13

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:24:58
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:41:40
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:07
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '11 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:50:13

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:24:58
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:41:40
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:07
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:50:13

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:24:58
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:41:40
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:07
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:50:13

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:24:58
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:41:40
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:07
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '15 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:50:13

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:24:58
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:41:40
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:34:07
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:50:13

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:24:58
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:41:40
User entered empty.	System	22 Feb 2021 16:50:13

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:41:40
User entered empty.	System	22 Feb 2021 16:50:13

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:41:40
User entered empty.	System	22 Feb 2021 16:50:13

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:24:58
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:42:04
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:31:17
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:09:59
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 Mar 2021 22:09:59
Data point term sent to Coder	System	18 Mar 2021 22:08:38
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 08:04:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 08:04:37
Data point term sent to Coder	System	22 Feb 2021 16:51:38
User entered 'heparin'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:51:06

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:24:58
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:42:04
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:31:17
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:51:06

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:24:58
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:42:04
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:31:17
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'small bowel obstruction'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:51:06

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:24:58
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:42:04
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:31:17
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '5000'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:51:06

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:24:58
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:42:04
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:31:17
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Other (OTHER)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:51:06

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:24:58
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:42:04
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:31:17
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'units'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:51:06

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:24:58
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:42:04
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:31:17
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'three times daily (TID)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:51:06

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:24:58
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:42:04
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:31:17
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:51:06

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:24:58
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:42:04
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:31:17
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Subcutaneous (SUBCUTANEOUS)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:51:06

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:24:58
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:42:04
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:31:17
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:51:06

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:24:58
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:42:04
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:31:17
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '11 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:51:06

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:24:58
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:42:04
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:31:17
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:51:06

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:24:58
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:42:04
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:31:17
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:51:06

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:24:58
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:42:04
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:31:17
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '16 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:51:06

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:24:58
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:42:04
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:31:17
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:51:06

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:24:58
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:42:04
User entered '3'	System	22 Feb 2021 16:51:06

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:42:04
User entered '1'	System	22 Feb 2021 16:51:06

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:42:04
User entered '804 (804)'	System	22 Feb 2021 16:51:06

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:24:58
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:42:29
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:30:34
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:09:35
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 Mar 2021 22:09:35
Data point term sent to Coder	System	18 Mar 2021 22:08:41
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 16:53:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 16:53:01
Data point term sent to Coder	System	22 Feb 2021 16:52:41
User entered 'fentanyl'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:52:14

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:24:58
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:42:29
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:30:34
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:52:14

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:24:58
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:42:29
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:30:34
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'small bowel obstruction'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:52:14

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:24:58
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:42:29
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:30:34
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '50'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:52:14

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:24:58
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:42:29
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:30:34
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'ug (ug)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:52:14

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:24:58
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:42:29
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:30:34
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:52:14

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:24:58
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:42:29
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:30:34
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'once (ONCE)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:52:14

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:24:58
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:42:29
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:30:34
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:52:14

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:24:58
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:42:29
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:30:34
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Intravenous (INTRAVENOUS)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:52:14

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:24:58
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:42:29
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:30:34
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:52:14

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:24:58
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:42:29
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:30:34
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '11 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:52:14

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:24:58
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:42:29
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:30:34
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:52:14

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:24:58
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:42:29
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:30:34
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:52:14

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:24:58
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:42:29
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:30:34
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '11 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:52:14

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:24:58
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:42:29
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:30:34
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:52:14

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:24:58
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:42:29
User entered empty.	System	22 Feb 2021 16:52:14

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:42:29
User entered empty.	System	22 Feb 2021 16:52:14

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:42:29
User entered empty.	System	22 Feb 2021 16:52:14

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:24:58
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:42:54
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 15:52:04
User coded data point as ATC: VARIOUS, ATC: CONTRAST MEDIA, ATC: X-RAY CONTRAST MEDIA, IODINATED, ATC: WATERSOLUBLE, NEPHROTROPIC, HIGH OSMOLAR X-RAY CONTRAST MEDIA, PRODUCT: MEGLUMINE AMIDOTRIZOATE;SODIUM AMIDOTRIZOATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:09:46
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 Mar 2021 22:09:46
Data point term sent to Coder	System	18 Mar 2021 22:08:41
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User coded data point as ATC: VARIOUS, ATC: CONTRAST MEDIA, ATC: X-RAY CONTRAST MEDIA, IODINATED, ATC: WATERSOLUBLE, NEPHROTROPIC, HIGH OSMOLAR X-RAY CONTRAST MEDIA, PRODUCT: MEGLUMINE AMIDOTRIZOATE;SODIUM AMIDOTRIZOATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 21:33:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 21:33:03
Data point term sent to Coder	System	22 Feb 2021 16:54:43
User entered 'diatrizoate meglumine ; comb; diatrizoate sodium'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:53:58

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:24:58
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:42:54
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 15:52:04
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:53:58

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:24:58
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:42:54
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 15:52:04
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'small bowel obstruction'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:53:58

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:24:58
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:42:54
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 15:52:04
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '120'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:53:58

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:24:58
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:42:54
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 15:52:04
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'mL (mL)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:53:58

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:24:58
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:42:54
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 15:52:04
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:53:58

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:24:58
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:42:54
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 15:52:04
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	22 Feb 2021 17:22:56
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	22 Feb 2021 17:22:56
User entered 'as needed (PRN)' reason for change: Data Entry Error	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:22:56
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	22 Feb 2021 16:53:58
User entered 'once (ONCE)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:53:58

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:24:58
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:42:54
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 15:52:04
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:53:58

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:24:58
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:42:54
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 15:52:04
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Oral (ORAL)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:53:58

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:24:58
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:42:54
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 15:52:04
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:53:58

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:24:58
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:42:54
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 15:52:04
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '11 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:53:58

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:24:58
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:42:54
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 15:52:04
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:53:58

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:24:58
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:42:54
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 15:52:04
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:53:58

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:24:58
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:42:54
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 15:52:04
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '12 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:53:58

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:24:58
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:42:54
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 15:52:04
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:53:58

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:24:58
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:42:54
User entered empty.	System	22 Feb 2021 16:53:58

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:42:54
User entered empty.	System	22 Feb 2021 16:53:58

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:42:54
User entered empty.	System	22 Feb 2021 16:53:58

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 10 Jun 2021 09:24:58
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:43:22
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:35:41
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: THROAT PREPARATIONS, ATC: THROAT PREPARATIONS, ATC: ANTISEPTICS, PRODUCT: PHENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 11:35:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 11:35:31
Data point term sent to Coder	System	18 Mar 2021 22:08:39
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
Data point term sent to Coder	System	22 Feb 2021 16:57:46
User entered 'phenol 1.4%'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:56:58

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 10 Jun 2021 09:24:58
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:43:22
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:35:41
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:56:58

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 10 Jun 2021 09:24:58
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:43:22
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:35:41
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'sore throat due to ng tube placement'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:56:58

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 10 Jun 2021 09:24:58
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:43:22
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:35:41
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '5'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:56:58

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 10 Jun 2021 09:24:58
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:43:22
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:35:41
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Other (OTHER)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:56:58

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 10 Jun 2021 09:24:58
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:43:22
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:35:41
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'sprays'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:56:58

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 10 Jun 2021 09:24:58
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:43:22
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:35:41
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'as needed (PRN)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:56:58

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 10 Jun 2021 09:24:58
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:43:22
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:35:41
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:56:58

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 10 Jun 2021 09:24:58
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:43:22
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:35:41
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Topical (TOPICAL)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:56:58

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 10 Jun 2021 09:24:58
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:43:22
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:35:41
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:56:58

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 10 Jun 2021 09:24:58
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:43:22
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:35:41
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '12 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:56:58

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 10 Jun 2021 09:24:58
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:43:22
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:35:41
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:56:58

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 10 Jun 2021 09:24:58
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:43:22
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:35:41
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:56:58

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 10 Jun 2021 09:24:58
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:43:22
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:35:41
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '16 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:56:58

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 10 Jun 2021 09:24:58
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:43:22
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:35:41
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:56:58

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 10 Jun 2021 09:24:58
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:43:22
User entered empty.	System	22 Feb 2021 16:56:58

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:43:22
User entered empty.	System	22 Feb 2021 16:56:58

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:43:22
User entered empty.	System	22 Feb 2021 16:56:58

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 10 Jun 2021 09:24:58
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:43:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:23:38
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE INACT SPLIT 4V, PRODUCTSYNONYM: QUADRIVALENT INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:09:31
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 Mar 2021 22:09:31
Data point term sent to Coder	System	18 Mar 2021 22:08:39
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE INACT SPLIT 4V, PRODUCTSYNONYM: QUADRIVALENT INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 17:00:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 17:00:02
Data point term sent to Coder	System	22 Feb 2021 16:58:47
User entered 'influenza quadrivalent'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:58:14

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 10 Jun 2021 09:24:58
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:43:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:23:38
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:58:14

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 10 Jun 2021 09:24:58
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:43:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:23:38
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'seasonal flu vaccine'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:58:14

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 10 Jun 2021 09:24:58
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:43:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:23:38
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0.5'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:58:14

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 10 Jun 2021 09:24:58
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:43:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:23:38
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'mL (mL)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:58:14

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 10 Jun 2021 09:24:58
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:43:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:23:38
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:58:14

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 10 Jun 2021 09:24:58
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:43:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:23:38
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'once (ONCE)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:58:14

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 10 Jun 2021 09:24:58
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:43:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:23:38
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:58:14

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 10 Jun 2021 09:24:58
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:43:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:23:38
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Intramuscular (INTRAMUSCULAR)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:58:14

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 10 Jun 2021 09:24:58
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:43:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:23:38
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:58:14

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 10 Jun 2021 09:24:58
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:43:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:23:38
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '12 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:58:14

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 10 Jun 2021 09:24:58
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:43:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:23:38
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:58:14

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 10 Jun 2021 09:24:58
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:43:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:23:38
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:58:14

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 10 Jun 2021 09:24:58
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:43:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:23:38
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '12 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:58:14

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 10 Jun 2021 09:24:58
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:43:49
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:23:38
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:58:14

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 10 Jun 2021 09:24:58
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:43:49
User entered empty.	System	22 Feb 2021 16:58:14

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:43:49
User entered empty.	System	22 Feb 2021 16:58:14

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:43:49
User entered empty.	System	22 Feb 2021 16:58:14

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 10 Jun 2021 09:24:58
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:44:18
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:24:14
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE HYDROCHLORIDE, PRODUCTSYNONYM: HYDROMORPHONE HCL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:09:41
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 Mar 2021 22:09:41
Data point term sent to Coder	System	18 Mar 2021 22:08:41
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE HYDROCHLORIDE, PRODUCTSYNONYM: HYDROMORPHONE HCL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 17:01:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 17:01:01
Data point term sent to Coder	System	22 Feb 2021 16:59:48
User entered 'hydromorphone hcl'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:59:23

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 10 Jun 2021 09:24:58
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:44:18
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:24:14
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:59:23

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 10 Jun 2021 09:24:58
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:44:18
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:24:14
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'small bowel obstruction'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:59:23

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 10 Jun 2021 09:24:58
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:44:18
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:24:14
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0.3'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:59:23

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 10 Jun 2021 09:24:58
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:44:18
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:24:14
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'mg (mg)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:59:23

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 10 Jun 2021 09:24:58
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:44:18
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:24:14
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:59:23

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 10 Jun 2021 09:24:58
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:44:18
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:24:14
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'other (OTHER)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:59:23

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 10 Jun 2021 09:24:58
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:44:18
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:24:14
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'every 4 to 6 hours as needed'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:59:23

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 10 Jun 2021 09:24:58
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:44:18
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:24:14
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Intravenous (INTRAVENOUS)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:59:23

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 10 Jun 2021 09:24:58
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:44:18
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:24:14
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:59:23

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 10 Jun 2021 09:24:58
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:44:18
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:24:14
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '12 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:59:23

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 10 Jun 2021 09:24:58
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:44:18
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:24:14
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:59:23

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 10 Jun 2021 09:24:58
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:44:18
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:24:14
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:59:23

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 10 Jun 2021 09:24:58
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:44:18
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:24:14
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '13 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:59:23

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 10 Jun 2021 09:24:58
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:44:18
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:24:14
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:59:23

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 10 Jun 2021 09:24:58
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:44:18
User entered empty.	System	22 Feb 2021 16:59:23

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:44:18
User entered empty.	System	22 Feb 2021 16:59:23

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:44:18
User entered empty.	System	22 Feb 2021 16:59:23

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 10 Jun 2021 09:24:58
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:44:47
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:26:01
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ARTERIOLAR SMOOTH MUSCLE, AGENTS ACTING ON, ATC: HYDRAZINOPHTHALAZINE DERIVATIVES, PRODUCT: HYDRALAZINE HYDROCHLORIDE, PRODUCTSYNONYM: HYDRALAZINE HCL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:09:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:09:59
Data point term sent to Coder	System	18 Mar 2021 22:08:46
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ARTERIOLAR SMOOTH MUSCLE, AGENTS ACTING ON, ATC: HYDRAZINOPHTHALAZINE DERIVATIVES, PRODUCT: HYDRALAZINE HYDROCHLORIDE, PRODUCTSYNONYM: HYDRALAZINE HCL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 17:03:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 17:03:00
Data point term sent to Coder	System	22 Feb 2021 17:01:50
User entered 'hydralazine hcl'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:01:06

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 10 Jun 2021 09:24:58
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:44:47
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:26:01
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:01:06

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 10 Jun 2021 09:24:58
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:44:47
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:26:01
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'worsening htn'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:01:06

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 10 Jun 2021 09:24:58
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:44:47
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:26:01
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '10'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:01:06

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 10 Jun 2021 09:24:58
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:44:47
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:26:01
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'mg (mg)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:01:06

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 10 Jun 2021 09:24:58
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:44:47
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:26:01
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:01:06

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 10 Jun 2021 09:24:58
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:44:47
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:26:01
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'as needed (PRN)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:01:06

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 10 Jun 2021 09:24:58
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:44:47
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:26:01
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:01:06

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 10 Jun 2021 09:24:58
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:44:47
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:26:01
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Intravenous (INTRAVENOUS)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:01:06

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 10 Jun 2021 09:24:58
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:44:47
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:26:01
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:01:06

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 10 Jun 2021 09:24:58
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:44:47
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:26:01
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '12 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:01:06

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 10 Jun 2021 09:24:58
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:44:47
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:26:01
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:01:06

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 10 Jun 2021 09:24:58
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:44:47
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:26:01
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:01:06

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 10 Jun 2021 09:24:58
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:44:47
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:26:01
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '15 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:01:06

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 10 Jun 2021 09:24:58
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:44:47
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:26:01
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:01:06

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 10 Jun 2021 09:24:58
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:44:47
User entered empty.	System	22 Feb 2021 17:01:06

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:44:47
User entered empty.	System	22 Feb 2021 17:01:06

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:44:47
User entered empty.	System	22 Feb 2021 17:01:06

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 10 Jun 2021 09:24:58
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:45:14
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:25:49
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ARTERIOLAR SMOOTH MUSCLE, AGENTS ACTING ON, ATC: HYDRAZINOPHTHALAZINE DERIVATIVES, PRODUCT: HYDRALAZINE HYDROCHLORIDE, PRODUCTSYNONYM: HYDRALAZINE HCL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:09:36
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 Mar 2021 22:09:36
Data point term sent to Coder	System	18 Mar 2021 22:08:44
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ARTERIOLAR SMOOTH MUSCLE, AGENTS ACTING ON, ATC: HYDRAZINOPHTHALAZINE DERIVATIVES, PRODUCT: HYDRALAZINE HYDROCHLORIDE, PRODUCTSYNONYM: HYDRALAZINE HCL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 17:04:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 17:04:02
Data point term sent to Coder	System	22 Feb 2021 17:02:51
User entered 'hydralazine hcl'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:02:19

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 10 Jun 2021 09:24:58
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:45:14
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:25:49
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:02:19

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 10 Jun 2021 09:24:58
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:45:14
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:25:49
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'small bowel obstruction'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:02:19

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 10 Jun 2021 09:24:58
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:45:14
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:25:49
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '20'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:02:19

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 10 Jun 2021 09:24:58
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:45:14
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:25:49
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Other (OTHER)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:02:19

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 10 Jun 2021 09:24:58
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:45:14
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:25:49
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'mg/mL'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:02:19

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 10 Jun 2021 09:24:58
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:45:14
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:25:49
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'other (OTHER)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:02:19

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 10 Jun 2021 09:24:58
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:45:14
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:25:49
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'every 4 to six hours as needed'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:02:19

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 10 Jun 2021 09:24:58
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:45:14
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:25:49
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Intravenous (INTRAVENOUS)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:02:19

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 10 Jun 2021 09:24:58
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:45:14
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:25:49
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:02:19

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 10 Jun 2021 09:24:58
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:45:14
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:25:49
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '12 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:02:19

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 10 Jun 2021 09:24:58
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:45:14
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:25:49
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:02:19

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 10 Jun 2021 09:24:58
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:45:14
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:25:49
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:02:19

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 10 Jun 2021 09:24:58
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:45:14
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:25:49
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '15 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:02:19

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 10 Jun 2021 09:24:58
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:45:14
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:25:49
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:02:19

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 10 Jun 2021 09:24:58
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:45:14
User entered empty.	System	22 Feb 2021 17:02:19

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:45:14
User entered empty.	System	22 Feb 2021 17:02:19

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:45:14
User entered empty.	System	22 Feb 2021 17:02:19

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 10 Jun 2021 09:24:58
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:45:40
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:29:30
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)	18 Mar 2021 22:09:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:09:40
Data point term sent to Coder	System	18 Mar 2021 22:08:47
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
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)	22 Feb 2021 17:05:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 17:05:01
Data point term sent to Coder	System	22 Feb 2021 17:03:52
User entered 'tylenol'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:03:03

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 10 Jun 2021 09:24:58
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:45:40
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:29:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:03:03

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 10 Jun 2021 09:24:58
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:45:40
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:29:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'small bowel obstruction'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:03:03

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 10 Jun 2021 09:24:58
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:45:40
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:29:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '975'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:03:03

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 10 Jun 2021 09:24:58
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:45:40
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:29:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'mg (mg)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:03:03

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 10 Jun 2021 09:24:58
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:45:40
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:29:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:03:03

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 10 Jun 2021 09:24:58
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:45:40
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:29:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'other (OTHER)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:03:03

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 10 Jun 2021 09:24:58
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:45:40
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:29:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'every 8 hours'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:03:03

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 10 Jun 2021 09:24:58
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:45:40
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:29:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Oral (ORAL)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:03:03

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 10 Jun 2021 09:24:58
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:45:40
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:29:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:03:03

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 10 Jun 2021 09:24:58
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:45:40
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:29:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '13 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:03:03

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 10 Jun 2021 09:24:58
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:45:40
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:29:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:03:03

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 10 Jun 2021 09:24:58
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:45:40
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:29:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:03:03

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 10 Jun 2021 09:24:58
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:45:40
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:29:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '15 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:03:03

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 10 Jun 2021 09:24:58
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:45:40
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:29:30
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:03:03

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 10 Jun 2021 09:24:58
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:45:40
User entered empty.	System	22 Feb 2021 17:03:03

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:45:40
User entered empty.	System	22 Feb 2021 17:03:03

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (26)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:45:40
User entered empty.	System	22 Feb 2021 17:03:03

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 10 Jun 2021 09:24:58
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:33:12
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 09:12:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 09:12:39
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 18:49:29
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 Mar 2021 18:49:29
Data point term sent to Coder	System	25 Mar 2021 18:48:28
Coding entries removed.	michelle saemann (b) (4) (b) (4)	25 Mar 2021 18:48:07
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:28:17
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:09:34
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 Mar 2021 22:09:34
Data point term sent to Coder	System	18 Mar 2021 22:08:46
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25

FDA-CBER-2022-1614-2920806

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 10 Jun 2021 09:24:58
Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 07:29:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 07:29:08
Data point term sent to Coder	System	22 Feb 2021 17:04:53
User entered 'potassium chloride'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:04:21

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 10 Jun 2021 09:24:58
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:33:12
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:28:17
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:04:21

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 10 Jun 2021 09:24:58
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:33:12
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 15:46:46
DataPoint Un-verified.	michelle saemann (b) (4)	25 Mar 2021 18:48:07
Signature has been broken.	michelle saemann (b) (4)	25 Mar 2021 18:48:07
User entered 'hypokalemia' reason for change: New Information	michelle saemann (b) (4)	25 Mar 2021 18:48:07
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:28:17
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
User entered 'small bowel obstruction'	Angela Snyder (b) (4)	22 Feb 2021 17:04:21

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 10 Jun 2021 09:24:58
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:33:12
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:28:17
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '10'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:04:21

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 10 Jun 2021 09:24:58
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:33:12
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:28:17
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Other (OTHER)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:04:21

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 10 Jun 2021 09:24:58
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:33:12
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:28:17
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'meq'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:04:21

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 10 Jun 2021 09:24:58
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:33:12
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:28:17
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'other (OTHER)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:04:21

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 10 Jun 2021 09:24:58
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:33:12
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:28:17
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'every hour'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:04:21

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 10 Jun 2021 09:24:58
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:33:12
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:28:17
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Intravenous (INTRAVENOUS)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:04:21

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 10 Jun 2021 09:24:58
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:33:12
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:28:17
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:04:21

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 10 Jun 2021 09:24:58
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:33:12
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:28:17
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '13 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:04:21

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 10 Jun 2021 09:24:58
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:33:12
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:28:17
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:04:21

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 10 Jun 2021 09:24:58
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:33:12
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:28:17
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:04:21

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 10 Jun 2021 09:24:58
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:33:12
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:28:17
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '13 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:04:21

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 10 Jun 2021 09:24:58
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:33:12
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:28:17
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:04:21

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 10 Jun 2021 09:24:58
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:33:12
User entered empty.	System	22 Feb 2021 17:04:21

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:33:12
User entered empty.	System	22 Feb 2021 17:04:21

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:33:12
User entered empty.	System	22 Feb 2021 17:04:21

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 10 Jun 2021 09:24:58
Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:28:50
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)	23 Mar 2021 15:08:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Mar 2021 15:08:37
Data point term sent to Coder	System	23 Mar 2021 15:08:05
Coding entries removed.	MaKayla Bishop (b) (4) (b) (4)	23 Mar 2021 15:07:48
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)	18 Mar 2021 22:09:46
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 Mar 2021 22:09:46
Data point term sent to Coder	System	18 Mar 2021 22:08:47
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
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)	22 Feb 2021 17:06:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 17:06:00
Data point term sent to Coder	System	22 Feb 2021 17:05:54
User entered 'miralax'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:05:13

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 10 Jun 2021 09:24:58
Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:28:50
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:05:13

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 10 Jun 2021 09:24:58
Indication

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:28:50
Signature has been broken.	MaKayla Bishop (b) (4) (b) (4)	23 Mar 2021 15:07:48
User entered 'SMALL BOWEL OBSTRUCTION/ prevention of reoccurrence' reason for change: Data Entry Error	MaKayla Bishop (b) (4) (b) (4)	23 Mar 2021 15:07:48
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'small bowel obstruction'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:05:13

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 10 Jun 2021 09:24:58
Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:28:50
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '17'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:05:13

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 10 Jun 2021 09:24:58
Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:28:50
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'g (g)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:05:13

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 10 Jun 2021 09:24:58
If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:28:50
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:05:13

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 10 Jun 2021 09:24:58
Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:28:50
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'once daily (QD)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:05:13

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 10 Jun 2021 09:24:58
If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:28:50
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:05:13

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 10 Jun 2021 09:24:58
Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:28:50
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Oral (ORAL)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:05:13

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 10 Jun 2021 09:24:58
If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:28:50
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:05:13

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 10 Jun 2021 09:24:58
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:28:50
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '14 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:05:13

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 10 Jun 2021 09:24:58
Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:28:50
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:05:13

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 10 Jun 2021 09:24:58
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:28:50
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)	24 Mar 2021 17:55:24
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 'still ongoing. indication updated. ' (Site from DM).	MaKayla Bishop (b) (4) (b) (4)	23 Mar 2021 15:08:26
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)	19 Mar 2021 11:24:33
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:05:13

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 10 Jun 2021 09:24:58
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:28:50
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:05:13

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 10 Jun 2021 09:24:58
Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:28:50
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:05:13

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 10 Jun 2021 09:24:58
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	22 Feb 2021 17:05:13

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	22 Feb 2021 17:05:13

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Feb 2021 17:05:13

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 10 Jun 2021 09:24:58
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:36:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:37:09
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: MELATONIN RECEPTOR AGONISTS, PRODUCT: MELATONIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:09:53
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 Mar 2021 22:09:53
Data point term sent to Coder	System	18 Mar 2021 22:08:48
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: MELATONIN RECEPTOR AGONISTS, PRODUCT: MELATONIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 17:07:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 17:07:03
Data point term sent to Coder	System	22 Feb 2021 17:06:55
User entered 'melatonin'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:06:01

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 10 Jun 2021 09:24:58
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:36:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:37:09
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:06:01

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 10 Jun 2021 09:24:58
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:36:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:37:09
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'insomnia'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:06:01

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 10 Jun 2021 09:24:58
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:36:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:37:09
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '3'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:06:01

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 10 Jun 2021 09:24:58
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:36:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:37:09
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'mg (mg)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:06:01

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 10 Jun 2021 09:24:58
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:36:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:37:09
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:06:01

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 10 Jun 2021 09:24:58
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:36:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:37:09
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'once daily (QD)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:06:01

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 10 Jun 2021 09:24:58
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:36:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:37:09
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:06:01

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 10 Jun 2021 09:24:58
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:36:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:37:09
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Oral (ORAL)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:06:01

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 10 Jun 2021 09:24:58
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:36:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:37:09
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:06:01

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 10 Jun 2021 09:24:58
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:36:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:37:09
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '14 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:06:01

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 10 Jun 2021 09:24:58
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:36:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:37:09
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:06:01

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 10 Jun 2021 09:24:58
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:36:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:37:09
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:06:01

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 10 Jun 2021 09:24:58
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:36:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:37:09
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '15 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:06:01

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 10 Jun 2021 09:24:58
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:36:27
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:37:09
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:06:01

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 10 Jun 2021 09:24:58
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:36:27
User entered '1'	System	22 Feb 2021 17:06:01

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:36:27
User entered '1'	System	22 Feb 2021 17:06:01

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:36:27
User entered '804 (804)'	System	22 Feb 2021 17:06:01

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (30)
Generated On: 10 Jun 2021 09:24:58
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:37:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:38:11
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: SYMPATHOMIMETICS, PLAIN, PRODUCT: PHENYLEPHRINE HYDROCHLORIDE, PRODUCTSYNONYM: AFRIN NASAL DECONGESTANT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:24:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:24:52
Data point term sent to Coder	System	18 Mar 2021 22:08:48
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: SYMPATHOMIMETICS, PLAIN, PRODUCT: PHENYLEPHRINE HYDROCHLORIDE, PRODUCTSYNONYM: AFRIN NASAL DECONGESTANT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 17:10:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 17:10:00
Data point term sent to Coder	System	22 Feb 2021 17:07:57
User entered 'afrin nasal solution 0.05%'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:06:58

FDA-CBER-2022-1614-2920861

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (30)
Generated On: 10 Jun 2021 09:24:58
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:37:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:38:11
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:06:58

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (30)
Generated On: 10 Jun 2021 09:24:58
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:37:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:38:11
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'sinusitis'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:06:58

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (30)
Generated On: 10 Jun 2021 09:24:58
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:37:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:38:11
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '2'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:06:58

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (30)
Generated On: 10 Jun 2021 09:24:58
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:37:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:38:11
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Other (OTHER)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:06:58

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (30)
Generated On: 10 Jun 2021 09:24:58
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:37:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:38:11
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'sprays'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:06:58

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (30)
Generated On: 10 Jun 2021 09:24:58
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:37:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:38:11
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'twice daily (BID)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:06:58

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (30)
Generated On: 10 Jun 2021 09:24:58
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:37:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:38:11
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:06:58

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (30)
Generated On: 10 Jun 2021 09:24:58
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:37:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:38:11
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Nasal (NASAL)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:06:58

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (30)
Generated On: 10 Jun 2021 09:24:58
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:37:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:38:11
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:06:58

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (30)
Generated On: 10 Jun 2021 09:24:58
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:37:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:38:11
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '14 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:06:58

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (30)
Generated On: 10 Jun 2021 09:24:58
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:37:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:38:11
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:06:58

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (30)
Generated On: 10 Jun 2021 09:24:58
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:37:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:38:11
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:06:58

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (30)
Generated On: 10 Jun 2021 09:24:58
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:37:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:38:11
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '16 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:06:58

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (30)
Generated On: 10 Jun 2021 09:24:58
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:37:19
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:38:11
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:06:58

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (30)
Generated On: 10 Jun 2021 09:24:58
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:37:19
User entered '2'	System	22 Feb 2021 17:06:58

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (30)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:37:19
User entered '1'	System	22 Feb 2021 17:06:58

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (30)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:37:19
User entered '804 (804)'	System	22 Feb 2021 17:06:58

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (31)
Generated On: 10 Jun 2021 09:24:58
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 17:10:59
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: DOCUSATE;SENNA ALEXANDRINA, PRODUCTSYNONYM: DOCUSATE;SENNA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 09:50:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 09:50:41
Data point term sent to Coder	System	07 Apr 2021 18:31:59
DataPoint Un-verified.	MaKayla Bishop (b) (4) (b) (4)	07 Apr 2021 18:31:39
Coding entries removed.	MaKayla Bishop (b) (4) (b) (4)	07 Apr 2021 18:31:39
Signature has been broken.	MaKayla Bishop (b) (4) (b) (4)	07 Apr 2021 18:31:39
User entered 'SENNA-DOCUSATE' reason for change: Data Entry Error	MaKayla Bishop (b) (4) (b) (4)	07 Apr 2021 18:31:39
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: SENNA ALEXANDRINA EXTRACT, PRODUCTSYNONYM: SENNA CONCENTRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 08:47:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 08:47:51
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:39:26
Data point term sent to Coder	System	23 Mar 2021 15:12:21
Coding entries removed.	MaKayla Bishop (b) (4) (b) (4)	23 Mar 2021 15:11:44

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (31)
Generated On: 10 Jun 2021 09:24:58
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: CONTACT LAXATIVES, PRODUCT: SENNA ALEXANDRINA EXTRACT, PRODUCTSYNONYM: SENNA CONCENTRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 09:36:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 09:36:29
Data point term sent to Coder	System	18 Mar 2021 22:08:47
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
Data point term sent to Coder	System	22 Feb 2021 17:08:59
User entered 'senna concentrate, standardized'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:08:23

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (31)
Generated On: 10 Jun 2021 09:24:58
Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:39:26
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:08:23

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (31)
Generated On: 10 Jun 2021 09:24:58
Indication

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:39:26
Signature has been broken.	MaKayla Bishop (b) (4) (b) (4)	23 Mar 2021 15:11:44
User entered 'SMALL BOWEL OBSTRUCTION/ prevention of reoccurrence' reason for change: Data Entry Error	MaKayla Bishop (b) (4) (b) (4)	23 Mar 2021 15:11:44
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'small bowel obstruction'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:08:23

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (31)
Generated On: 10 Jun 2021 09:24:58
Dose per administration

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review dose if this is a combination drug. If yes, please update medication name to include all components. If no, please update dose as this is not the standard dose for this medication. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 07:39:59
Query 'Per DM CLR: Please review dose if this is a combination drug. If yes, please update medication name to include all components. If no, please update dose as this is not the standard dose for this medication. Otherwise, clarify. ' answered with 'UPDATED. ' (Site from DM).	MaKayla Bishop (b) (4) (b) (4)	07 Apr 2021 18:32:27
User opened query 'Per DM CLR: Please review dose if this is a combination drug. If yes, please update medication name to include all components. If no, please update dose as this is not the standard dose for this medication. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 06:57:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:39:26
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '8.6-50'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:08:23

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (31)
Generated On: 10 Jun 2021 09:24:58
Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:39:26
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'mg (mg)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:08:23

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (31)
Generated On: 10 Jun 2021 09:24:58
If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:39:26
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:08:23

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (31)
Generated On: 10 Jun 2021 09:24:58
Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:39:26
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'once daily (QD)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:08:23

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (31)
Generated On: 10 Jun 2021 09:24:58
If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:39:26
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:08:23

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (31)
Generated On: 10 Jun 2021 09:24:58
Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:39:26
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Oral (ORAL)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:08:23

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (31)
Generated On: 10 Jun 2021 09:24:58
If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:39:26
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:08:23

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (31)
Generated On: 10 Jun 2021 09:24:58
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:39:26
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '15 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:08:23

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (31)
Generated On: 10 Jun 2021 09:24:58
Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:39:26
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:08:23

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (31)
Generated On: 10 Jun 2021 09:24:58
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:39:26
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)	24 Mar 2021 17:54:54
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 'still ongoing, indication updated. ' (Site from DM).	MaKayla Bishop (b) (4) (b) (4)	23 Mar 2021 15:12:22
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)	19 Mar 2021 11:24:57
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:08:23

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (31)
Generated On: 10 Jun 2021 09:24:58
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:39:26
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:08:23

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (31)
Generated On: 10 Jun 2021 09:24:58
Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:39:26
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:08:23

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (31)
Generated On: 10 Jun 2021 09:24:58
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	22 Feb 2021 17:08:23

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (31)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	22 Feb 2021 17:08:23

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (31)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Feb 2021 17:08:23

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (32)
Generated On: 10 Jun 2021 09:24:58
Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN, PRODUCTSYNONYM: NEURONTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:18:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:18:25
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:41:41
Data point term sent to Coder	System	23 Mar 2021 15:10:15
Coding entries removed.	MaKayla Bishop (b) (4) (b) (4)	23 Mar 2021 15:09:41
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN, PRODUCTSYNONYM: NEURONTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:10:08
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 Mar 2021 22:10:08
Data point term sent to Coder	System	18 Mar 2021 22:08:48
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN, PRODUCTSYNONYM: NEURONTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 07:59:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 07:59:11
Data point term sent to Coder	System	22 Feb 2021 17:10:01
User entered 'gabapentin ; Neurontin'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:09:22

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (32)
Generated On: 10 Jun 2021 09:24:58
Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:41:41
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:09:22

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (32)
Generated On: 10 Jun 2021 09:24:58
Indication

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:41:41
Signature has been broken.	MaKayla Bishop (b) (4) (b) (4)	23 Mar 2021 15:09:41
User entered 'SMALL BOWEL OBSTRUCTION/ prevention of reoccurrence' reason for change: Data Entry Error	MaKayla Bishop (b) (4) (b) (4)	23 Mar 2021 15:09:41
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'small bowel obstruction'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:09:22

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (32)
Generated On: 10 Jun 2021 09:24:58
Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:41:41
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '100'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:09:22

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (32)
Generated On: 10 Jun 2021 09:24:58
Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:41:41
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'mg (mg)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:09:22

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (32)
Generated On: 10 Jun 2021 09:24:58
If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:41:41
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:09:22

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (32)
Generated On: 10 Jun 2021 09:24:58
Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:41:41
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'three times daily (TID)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:09:22

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (32)
Generated On: 10 Jun 2021 09:24:58
If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:41:41
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:09:22

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (32)
Generated On: 10 Jun 2021 09:24:58
Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:41:41
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Oral (ORAL)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:09:22

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (32)
Generated On: 10 Jun 2021 09:24:58
If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:41:41
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:09:22

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (32)
Generated On: 10 Jun 2021 09:24:58
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:41:41
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '15 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:09:22

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (32)
Generated On: 10 Jun 2021 09:24:58
Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:41:41
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:09:22

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (32)
Generated On: 10 Jun 2021 09:24:58
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:20:10
DataPoint Un-verified.	(b) (4), (b) (6)	24 Mar 2021 19:41:52
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:41:41
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)	24 Mar 2021 17:55:05
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 'still ongoing, indication updated. ' (Site from DM).	MaKayla Bishop (b) (4) (b) (4)	23 Mar 2021 15:10:39
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)	19 Mar 2021 11:25:06
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:09:22

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (32)
Generated On: 10 Jun 2021 09:24:58
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:20:12
User closed query 'per medical records only for 7days. End date should be 22-Feb-21. Please verify and update. ' (Site from CRA).	(b) (4), (b) (6)	05 Apr 2021 14:50:53
Query 'per medical records only for 7days. End date should be 22-Feb-21. Please verify and update. ' answered with 'pt states medication was continued per MD ' (Site from CRA).	MaKayla Bishop (b) (4) (b) (4)	25 Mar 2021 14:42:18
DataPoint Un-verified.	(b) (4), (b) (6)	24 Mar 2021 19:41:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:41:41
User opened query 'per medical records only for 7days. End date should be 22-Feb-21. Please verify and update. ' (Site from CRA).	(b) (4), (b) (6)	24 Mar 2021 19:40:48
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:09:22

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (32)
Generated On: 10 Jun 2021 09:24:58
Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:41:41
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:09:22

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (32)
Generated On: 10 Jun 2021 09:24:58
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '3'	System	22 Feb 2021 17:09:22

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (32)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	22 Feb 2021 17:09:22

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (32)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Feb 2021 17:09:22

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (33)
Generated On: 10 Jun 2021 09:24:58
Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:42:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Mar 2021 16:09:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Mar 2021 16:09:37
Data point term sent to Coder	System	23 Mar 2021 16:09:06
Coding entries removed.	Angela Snyder (b) (4) (b) (4)	23 Mar 2021 16:08:37
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:09:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:09:57
Data point term sent to Coder	System	18 Mar 2021 22:08:47
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 15:13:39

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (33)
Generated On: 10 Jun 2021 09:24:58
Name of Medication

Audit	User	Time (GMT)
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 Mar 2021 15:13:39
Data point term sent to Coder	System	08 Mar 2021 15:12:58
Coding entries removed.	Angela Snyder (b) (4) (b) (4)	08 Mar 2021 15:12:01
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 17:12:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 17:12:01
Data point term sent to Coder	System	22 Feb 2021 17:11:02
User entered 'zofran'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:10:16

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (33)
Generated On: 10 Jun 2021 09:24:58
Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:42:36
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:10:16

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (33)
Generated On: 10 Jun 2021 09:24:58
Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:42:36
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'nausea'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:10:16

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (33)
Generated On: 10 Jun 2021 09:24:58
Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:42:36
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '4'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:10:16

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (33)
Generated On: 10 Jun 2021 09:24:58
Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:42:36
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'mg (mg)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:10:16

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (33)
Generated On: 10 Jun 2021 09:24:58
If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:42:36
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:10:16

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (33)
Generated On: 10 Jun 2021 09:24:58
Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:42:36
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'as needed (PRN)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:10:16

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (33)
Generated On: 10 Jun 2021 09:24:58
If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:42:36
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:10:16

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (33)
Generated On: 10 Jun 2021 09:24:58
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:42:36
Signature has been broken.	Angela Snyder (b) (4) (b) (4)	23 Mar 2021 16:08:37
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Angela Snyder (b) (4) (b) (4)	23 Mar 2021 16:08:37
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Intravenous (INTRAVENOUS)' reason for change: Data Entry Error	Angela Snyder (b) (4) (b) (4)	08 Mar 2021 15:12:01
User entered 'Oral (ORAL)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:10:16

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (33)
Generated On: 10 Jun 2021 09:24:58
If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:42:36
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:10:16

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (33)
Generated On: 10 Jun 2021 09:24:58
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:42:36
Signature has been broken.	Angela Snyder (b) (4) (b) (4)	23 Mar 2021 16:08:37
User entered '16 Feb 2021' reason for change: Data Entry Error	Angela Snyder (b) (4) (b) (4)	23 Mar 2021 16:08:37
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '11 Feb 2021' reason for change: Data Entry Error	Angela Snyder (b) (4) (b) (4)	08 Mar 2021 15:12:01
User entered '16 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:10:16

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (33)
Generated On: 10 Jun 2021 09:24:58
Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:42:36
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:10:16

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (33)
Generated On: 10 Jun 2021 09:24:58
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:42:36
Signature has been broken.	Angela Snyder (b) (4) (b) (4)	23 Mar 2021 16:08:37
User entered 'Yes (Y)' reason for change: Data Entry Error	Angela Snyder (b) (4) (b) (4)	23 Mar 2021 16:08:37
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)' reason for change: Data Entry Error	Angela Snyder (b) (4) (b) (4)	08 Mar 2021 15:12:01
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:10:16

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (33)
Generated On: 10 Jun 2021 09:24:58
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:42:36
Signature has been broken.	Angela Snyder (b) (4) (b) (4)	23 Mar 2021 16:08:37
User entered empty; reason for change Data Entry Error	Angela Snyder (b) (4) (b) (4)	23 Mar 2021 16:08:37
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '16 Feb 2021' reason for change: Data Entry Error	Angela Snyder (b) (4) (b) (4)	08 Mar 2021 15:12:01
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:10:16

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (33)
Generated On: 10 Jun 2021 09:24:58
Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:42:36
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:10:16

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (33)
Generated On: 10 Jun 2021 09:24:58
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	22 Feb 2021 17:10:16

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (33)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	22 Feb 2021 17:10:16

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (33)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	22 Feb 2021 17:10:16

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (34)
Generated On: 10 Jun 2021 09:24:58
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:38:21
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:43:09
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE SODIUM SESQUIHYDRATE, PRODUCTSYNONYM: PROTONIX [PANTOPRAZOLE SODIUM SESQUIHYDRATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:24:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:24:54
Data point term sent to Coder	System	18 Mar 2021 22:08:49
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE SODIUM SESQUIHYDRATE, PRODUCTSYNONYM: PROTONIX [PANTOPRAZOLE SODIUM SESQUIHYDRATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 07:22:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 07:22:08
Data point term sent to Coder	System	22 Feb 2021 17:12:03
User entered 'pantoprazole ; protonix'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:11:16

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (34)
Generated On: 10 Jun 2021 09:24:58
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:38:21
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:43:09
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:11:16

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (34)
Generated On: 10 Jun 2021 09:24:58
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:38:21
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:43:09
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'small bowel obstruction'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:11:16

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (34)
Generated On: 10 Jun 2021 09:24:58
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:38:21
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:43:09
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '40'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:11:16

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (34)
Generated On: 10 Jun 2021 09:24:58
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:38:21
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:43:09
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'mg (mg)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:11:16

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (34)
Generated On: 10 Jun 2021 09:24:58
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:38:21
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:43:09
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:11:16

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (34)
Generated On: 10 Jun 2021 09:24:58
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:38:21
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:43:09
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'once (ONCE)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:11:16

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (34)
Generated On: 10 Jun 2021 09:24:58
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:38:21
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:43:09
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:11:16

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (34)
Generated On: 10 Jun 2021 09:24:58
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:38:21
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:43:09
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Oral (ORAL)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:11:16

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (34)
Generated On: 10 Jun 2021 09:24:58
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:38:21
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:43:09
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:11:16

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (34)
Generated On: 10 Jun 2021 09:24:58
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:38:21
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:43:09
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '16 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:11:16

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (34)
Generated On: 10 Jun 2021 09:24:58
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:38:21
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:43:09
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:11:16

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (34)
Generated On: 10 Jun 2021 09:24:58
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:38:21
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:43:09
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:11:16

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (34)
Generated On: 10 Jun 2021 09:24:58
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:38:21
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:43:09
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '16 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:11:16

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (34)
Generated On: 10 Jun 2021 09:24:58
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:38:21
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 19:43:09
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 17:11:16

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (34)
Generated On: 10 Jun 2021 09:24:58
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:38:21
User entered empty.	System	22 Feb 2021 17:11:16

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (34)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:38:21
User entered empty.	System	22 Feb 2021 17:11:16

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (34)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:38:21
User entered empty.	System	22 Feb 2021 17:11:16

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (35)
Generated On: 10 Jun 2021 09:24:58
Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:12:39
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Mar 2021 22:09:34
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 Mar 2021 22:09:34
Data point term sent to Coder	System	18 Mar 2021 22:08:49
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 13:42:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 13:42:56
Data point term sent to Coder	System	15 Mar 2021 13:42:25
User entered 'hydrochlorothiazide'	Angela Snyder (b) (4) (b) (4)	15 Mar 2021 13:42:03

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (35)
Generated On: 10 Jun 2021 09:24:58
Prophylaxis

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:12:39
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	15 Mar 2021 13:42:03

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (35)
Generated On: 10 Jun 2021 09:24:58
Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:12:39
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'hypertension'	Angela Snyder (b) (4) (b) (4)	15 Mar 2021 13:42:03

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (35)
Generated On: 10 Jun 2021 09:24:58
Dose per administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:12:39
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '12.5'	Angela Snyder (b) (4) (b) (4)	15 Mar 2021 13:42:03

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (35)
Generated On: 10 Jun 2021 09:24:58
Dose unit

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:12:39
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'mg (mg)'	Angela Snyder (b) (4) (b) (4)	15 Mar 2021 13:42:03

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (35)
Generated On: 10 Jun 2021 09:24:58
If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:12:39
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	15 Mar 2021 13:42:03

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (35)
Generated On: 10 Jun 2021 09:24:58
Frequency

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:12:39
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'once daily (QD)'	Angela Snyder (b) (4) (b) (4)	15 Mar 2021 13:42:03

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (35)
Generated On: 10 Jun 2021 09:24:58
If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:12:39
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	15 Mar 2021 13:42:03

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (35)
Generated On: 10 Jun 2021 09:24:58
Route of administration

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:12:39
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Oral (ORAL)'	Angela Snyder (b) (4) (b) (4)	15 Mar 2021 13:42:03

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (35)
Generated On: 10 Jun 2021 09:24:58
If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:12:39
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	15 Mar 2021 13:42:03

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (35)
Generated On: 10 Jun 2021 09:24:58
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:12:39
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '15 Mar 2021'	Angela Snyder (b) (4) (b) (4)	15 Mar 2021 13:42:03

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (35)
Generated On: 10 Jun 2021 09:24:58
Start date completely unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:12:39
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '0'	Angela Snyder (b) (4) (b) (4)	15 Mar 2021 13:42:03

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (35)
Generated On: 10 Jun 2021 09:24:58
Ongoing?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:12:39
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	15 Mar 2021 13:42:03

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (35)
Generated On: 10 Jun 2021 09:24:58
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:12:39
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	15 Mar 2021 13:42:03

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (35)
Generated On: 10 Jun 2021 09:24:58
Was this medication taken for solicited event?

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:12:39
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	15 Mar 2021 13:42:03

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (35)
Generated On: 10 Jun 2021 09:24:58
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	15 Mar 2021 13:42:03

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (35)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	15 Mar 2021 13:42:03

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (35)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Mar 2021 13:42:03

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (36)
Generated On: 10 Jun 2021 09:24:58
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:20
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:59:03
User coded data point as ATC: VARIOUS, ATC: CONTRAST MEDIA, ATC: X-RAY CONTRAST MEDIA, IODINATED, ATC: WATERSOLUBLE, NEPHROTROPIC, HIGH OSMOLAR X-RAY CONTRAST MEDIA, PRODUCT: MEGLUMINE AMIDOTRIZOATE;SODIUM AMIDOTRIZOATE, PRODUCTSYNONYM: GASTROGRAFIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:18:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:18:25
Data point term sent to Coder	System	25 Mar 2021 19:04:44
User entered 'GASTROGRAFIN (DIATRIZOATE MEGLUMINE AND SODIUM)' reason for change: Data Entry Error	michelle saemann (b) (4) (b) (4)	25 Mar 2021 19:04:17
Data point term sent to Coder	System	25 Mar 2021 19:03:42
User entered 'gastrografrafin (diatrizoate meglumine and sodium)'	michelle saemann (b) (4) (b) (4)	25 Mar 2021 19:03:05

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (36)
Generated On: 10 Jun 2021 09:24:58
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:20
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 15:59:03
User entered 'No (N)'	michelle saemann (b) (4)	25 Mar 2021 19:03:05

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (36)
Generated On: 10 Jun 2021 09:24:58
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:20
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:59:03
User entered 'NG tube placement, procedure'	michelle saemann (b) (4) (b) (4)	25 Mar 2021 19:03:05

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (36)
Generated On: 10 Jun 2021 09:24:58
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:20
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 15:59:03
User entered '120'	michelle saemann (b) (4)	25 Mar 2021 19:03:05

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (36)
Generated On: 10 Jun 2021 09:24:58
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:20
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 15:59:03
User entered 'mL (mL)'	michelle saemann (b) (4)	25 Mar 2021 19:03:05

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (36)
Generated On: 10 Jun 2021 09:24:58
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:20
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:59:03
User entered empty.	michelle saemann (b) (4) (b) (4)	25 Mar 2021 19:03:05

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (36)
Generated On: 10 Jun 2021 09:24:58
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:20
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 15:59:03
User entered 'once (ONCE)'	michelle saemann (b) (4)	25 Mar 2021 19:03:05

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (36)
Generated On: 10 Jun 2021 09:24:58
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:20
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:59:03
User entered empty.	michelle saemann (b) (4) (b) (4)	25 Mar 2021 19:03:05

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (36)
Generated On: 10 Jun 2021 09:24:58
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:20
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 15:59:03
User entered 'Other (OTHER)'	michelle saemann (b) (4)	25 Mar 2021 19:03:05

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (36)
Generated On: 10 Jun 2021 09:24:58
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:20
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 15:59:03
User entered 'via NG tube'	michelle saemann (b) (4)	25 Mar 2021 19:03:05

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (36)
Generated On: 10 Jun 2021 09:24:58
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:20
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 15:59:03
User entered '11 Feb 2021'	michelle saemann (b) (4)	25 Mar 2021 19:03:05

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (36)
Generated On: 10 Jun 2021 09:24:58
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:20
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 15:59:03
User entered '0'	michelle saemann (b) (4)	25 Mar 2021 19:03:05

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (36)
Generated On: 10 Jun 2021 09:24:58
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:20
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 15:59:03
User entered 'No (N)'	michelle saemann (b) (4)	25 Mar 2021 19:03:05

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (36)
Generated On: 10 Jun 2021 09:24:58
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:20
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:59:03
User entered '11 Feb 2021'	michelle saemann (b) (4) (b) (4)	25 Mar 2021 19:03:05

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (36)
Generated On: 10 Jun 2021 09:24:58
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:20
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 15:59:03
User entered 'No (N)'	michelle saemann (b) (4)	25 Mar 2021 19:03:05

FDA-CBER-2022-1614-2920985

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (36)
Generated On: 10 Jun 2021 09:24:58
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:20
User entered empty.	System	25 Mar 2021 19:03:05

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (36)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:20
User entered empty.	System	25 Mar 2021 19:03:05

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (36)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:29:20
User entered empty.	System	25 Mar 2021 19:03:05

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (37)
Generated On: 10 Jun 2021 09:24:58
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:11:51
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE HYDROCHLORIDE, PRODUCTSYNONYM: TRAZODONE HCL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 18:35:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 18:35:36
Data point term sent to Coder	System	07 Apr 2021 18:35:05
User entered 'trazodone hcl'	Angela Snyder (b) (4) (b) (4)	07 Apr 2021 18:35:04

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (37)
Generated On: 10 Jun 2021 09:24:58
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:11:51
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	07 Apr 2021 18:35:04

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (37)
Generated On: 10 Jun 2021 09:24:58
Indication

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:11:51
User entered 'anxiety/insomnia'	Angela Snyder (b) (4) (b) (4)	07 Apr 2021 18:35:04

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (37)
Generated On: 10 Jun 2021 09:24:58
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:11:51
User entered '50'	Angela Snyder (b) (4) (b) (4)	07 Apr 2021 18:35:04

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (37)
Generated On: 10 Jun 2021 09:24:58
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:11:51
User entered 'mg (mg)'	Angela Snyder (b) (4) (b) (4)	07 Apr 2021 18:35:04

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (37)
Generated On: 10 Jun 2021 09:24:58
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:11:51
User entered empty.	Angela Snyder (b) (4) (b) (4)	07 Apr 2021 18:35:04

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (37)
Generated On: 10 Jun 2021 09:24:58
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:11:51
User entered 'as needed (PRN)'	Angela Snyder (b) (4) (b) (4)	07 Apr 2021 18:35:04

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (37)
Generated On: 10 Jun 2021 09:24:58
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:11:51
User entered empty.	Angela Snyder (b) (4) (b) (4)	07 Apr 2021 18:35:04

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (37)
Generated On: 10 Jun 2021 09:24:58
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:11:51
User entered 'Oral (ORAL)'	Angela Snyder (b) (4) (b) (4)	07 Apr 2021 18:35:04

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (37)
Generated On: 10 Jun 2021 09:24:58
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:11:51
User entered empty.	Angela Snyder (b) (4) (b) (4)	07 Apr 2021 18:35:04

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (37)
Generated On: 10 Jun 2021 09:24:58
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:11:51
User entered '8 Sep 2017'	Angela Snyder (b) (4) (b) (4)	07 Apr 2021 18:35:04

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (37)
Generated On: 10 Jun 2021 09:24:58
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:11:51
User entered '0'	Angela Snyder (b) (4) (b) (4)	07 Apr 2021 18:35:04

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (37)
Generated On: 10 Jun 2021 09:24:58
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:11:51
User entered 'Yes (Y)'	Angela Snyder (b) (4) (b) (4)	07 Apr 2021 18:35:04

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (37)
Generated On: 10 Jun 2021 09:24:58
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:11:51
User entered empty.	Angela Snyder (b) (4) (b) (4)	07 Apr 2021 18:35:04

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (37)
Generated On: 10 Jun 2021 09:24:58
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 17:11:51
User entered 'No (N)'	Angela Snyder (b) (4) (b) (4)	07 Apr 2021 18:35:04

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (37)
Generated On: 10 Jun 2021 09:24:58
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 18:35:04

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (37)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 18:35:04

US3662116
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (37)
Generated On: 10 Jun 2021 09:24:58
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 18:35:04

US3662116
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Generated On: 10 Jun 2021 09:24:58
Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:26:54
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 16:59:59
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Un-verified.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:14:34
User entered 'Yes (Y)' reason for change: Data Entry Error	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:14:34
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:56:27
User entered 'No (N)'	Brenda Miller (b) (4) (b) (4)	22 Sep 2020 14:14:23

US3662116
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (1)
Generated On: 10 Jun 2021 09:24:58
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 15:16:45
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Un-verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:56:37
User entered '12 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:14:56

US3662116
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (1)
Generated On: 10 Jun 2021 09:24:58
Procedure/Surgery

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 15:16:45
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Un-verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:56:37
User entered 'picc placement'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:14:56

US3662116
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (1)
Generated On: 10 Jun 2021 09:24:58
Indication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 15:16:45
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Un-verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:56:37
User entered 'Adverse Event (AE)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:14:56

US3662116
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (1)
Generated On: 10 Jun 2021 09:24:58
If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 15:16:45
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Un-verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:01
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:56:37
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:14:56

US3662116
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (2)
Generated On: 10 Jun 2021 09:24:58
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:20
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 15:16:55
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Un-verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:00
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:56:50
User entered '11 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:15:24

US3662116
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (2)
Generated On: 10 Jun 2021 09:24:58
Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:20
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 15:16:55
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Un-verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:00
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:56:50
User entered 'ng tube placement'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:15:24

US3662116
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (2)
Generated On: 10 Jun 2021 09:24:58
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:20
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 15:16:55
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Un-verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:00
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:56:50
User entered 'Adverse Event (AE)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:15:24

US3662116
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (2)
Generated On: 10 Jun 2021 09:24:58
If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:20
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 15:16:55
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Un-verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:00
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:56:50
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:15:24

US3662116
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (3)
Generated On: 10 Jun 2021 09:24:58
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:25:52
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Un-verified.	(b) (4), (b) (6)	11 Mar 2021 19:56:58
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:56:52
User entered '11 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:15:50

US3662116
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (3)
Generated On: 10 Jun 2021 09:24:58
Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:25:52
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Un-verified.	(b) (4), (b) (6)	11 Mar 2021 19:56:58
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:56:52
User entered 'bedside focused fast ultrasound'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:15:50

US3662116
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (3)
Generated On: 10 Jun 2021 09:24:58
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:25:52
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Un-verified.	(b) (4), (b) (6)	11 Mar 2021 19:56:58
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:56:52
User entered 'Diagnostic (DIAGNOSTIC)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:15:50

US3662116
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (3)
Generated On: 10 Jun 2021 09:24:58
If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:24
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:25:52
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Un-verified.	(b) (4), (b) (6)	11 Mar 2021 19:56:58
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:56:52
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:15:50

US3662116
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (4)
Generated On: 10 Jun 2021 09:24:58
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:36
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:56:56
User entered '11 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:16:11

US3662116
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (4)
Generated On: 10 Jun 2021 09:24:58
Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:36
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:56:56
User entered 'xray portable chest'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:16:11

US3662116
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (4)
Generated On: 10 Jun 2021 09:24:58
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:36
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:56:56
User entered 'Diagnostic (DIAGNOSTIC)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:16:11

US3662116
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (4)
Generated On: 10 Jun 2021 09:24:58
If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:36
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:56:56
User entered empty.	Angela Snyder (b) (4)	22 Feb 2021 16:16:11

US3662116
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (5)
Generated On: 10 Jun 2021 09:24:58
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:58
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:12
User entered '11 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:17:53

US3662116
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (5)
Generated On: 10 Jun 2021 09:24:58
Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:58
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:12
User entered 'XRAY PORTABLE ABDOMEN ap VIEW' reason for change: Data Entry Error	Angela Snyder (b) (4)	22 Feb 2021 16:24:50
User entered 'XRAY PoRTABLE ABDOMEN VIEW' reason for change: Data Entry Error	Angela Snyder (b) (4)	22 Feb 2021 16:18:02
User entered 'xray prtable abdomen view'	Angela Snyder (b) (4)	22 Feb 2021 16:17:53

US3662116
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (5)
Generated On: 10 Jun 2021 09:24:58
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:58
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:12
User entered 'Diagnostic (DIAGNOSTIC)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:17:53

US3662116
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (5)
Generated On: 10 Jun 2021 09:24:58
If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:58
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:12
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:17:53

US3662116
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (6)
Generated On: 10 Jun 2021 09:24:58
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:54
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:24
User entered '11 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:18:36

US3662116
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (6)
Generated On: 10 Jun 2021 09:24:58
Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:24
User entered 'CT ANGIO CHEST With AND/OR without' reason for change: Data Entry Error	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:25:25
User entered 'ct angio chest wand or wo'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:18:36

US3662116
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (6)
Generated On: 10 Jun 2021 09:24:58
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:54
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:24
User entered 'Diagnostic (DIAGNOSTIC)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:18:36

US3662116
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (6)
Generated On: 10 Jun 2021 09:24:58
If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:54
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:24
User entered empty.	Angela Snyder (b) (4)	22 Feb 2021 16:18:36

US3662116
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (7)
Generated On: 10 Jun 2021 09:24:58
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:51
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:38
User entered '11 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:19:09

US3662116
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (7)
Generated On: 10 Jun 2021 09:24:58
Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:51
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:57:38
User entered 'CT ANGIO ABDomen PELVIS with AND/OR Without iv contrast' reason for change: Data Entry Error	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:26:09
User entered 'ct angio abd pelvis and or wo'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:19:09

US3662116
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (7)
Generated On: 10 Jun 2021 09:24:58
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:51
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:38
User entered 'Diagnostic (DIAGNOSTIC)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:19:09

US3662116
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (7)
Generated On: 10 Jun 2021 09:24:58
If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:51
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:38
User entered empty.	Angela Snyder (b) (4)	22 Feb 2021 16:19:09

US3662116
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (8)
Generated On: 10 Jun 2021 09:24:58
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:27:35
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered '11 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:19:34

US3662116
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (8)
Generated On: 10 Jun 2021 09:24:58
Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:27:35
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'xr portable feeding tube check'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:19:34

US3662116
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (8)
Generated On: 10 Jun 2021 09:24:58
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:27:35
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered 'Diagnostic (DIAGNOSTIC)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:19:34

US3662116
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (8)
Generated On: 10 Jun 2021 09:24:58
If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:48
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 18:27:35
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
User entered empty.	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:19:34

US3662116
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (9)
Generated On: 10 Jun 2021 09:24:58
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:45
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:56
User entered '12 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:20:05

US3662116
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (9)
Generated On: 10 Jun 2021 09:24:58
Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:45
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:56
User entered 'XRAY PORTABLE ABDOMINAL Ap VIEW' reason for change: Data Entry Error	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:26:25
User entered 'xray portable abdominal ad view'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:20:05

US3662116
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (9)
Generated On: 10 Jun 2021 09:24:58
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:45
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:56
User entered 'Adverse Event (AE)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:20:05

US3662116
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (9)
Generated On: 10 Jun 2021 09:24:58
If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:45
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:57:56
User entered empty.	Angela Snyder (b) (4)	22 Feb 2021 16:20:05

US3662116
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (10)
Generated On: 10 Jun 2021 09:24:58
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:42
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:58:13
User closed query 'Per DM CLR: Please review date of this Procedure as it overlaps with Procedure #5 XRAY PORTABLE ABDOMEN AP VIEW (11 FEB 2021). Verify and update start/end dates or remove duplicate entry as necessary. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 16:20:52
Query 'Per DM CLR: Please review date of this Procedure as it overlaps with Procedure #5 XRAY PORTABLE ABDOMEN AP VIEW (11 FEB 2021). Verify and update start/end dates or remove duplicate entry as necessary. ' answered with 'not a duplicated. Pt. had one at 0905 and one at 2030. ' (Site from DM).	michelle saemann (b) (4) (b) (4)	02 Mar 2021 14:18:43
User opened query 'Per DM CLR: Please review date of this Procedure as it overlaps with Procedure #5 XRAY PORTABLE ABDOMEN AP VIEW (11 FEB 2021). Verify and update start/end dates or remove duplicate entry as necessary. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 08:24:14
User entered '11 Feb 2021'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:20:50

US3662116
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (10)
Generated On: 10 Jun 2021 09:24:58
Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:42
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:58:13
User entered 'xray portable abdomen ap view'	Angela Snyder (b) (4)	22 Feb 2021 16:20:50

US3662116
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (10)
Generated On: 10 Jun 2021 09:24:58
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:42
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:58:13
User entered 'Diagnostic (DIAGNOSTIC)'	Angela Snyder (b) (4) (b) (4)	22 Feb 2021 16:20:50

US3662116
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (10)
Generated On: 10 Jun 2021 09:24:58
If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:42
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:58:13
User entered empty.	Angela Snyder (b) (4)	22 Feb 2021 16:20:50

US3662116
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (11)
Generated On: 10 Jun 2021 09:24:58
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:39
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:14:54
User entered '12 Feb 2021'	Angela Snyder (b) (4) (b) (4)	23 Mar 2021 15:48:09

US3662116
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (11)
Generated On: 10 Jun 2021 09:24:58
Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:39
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:14:54
User entered 'ecg 12 lead'	Angela Snyder (b) (4) (b) (4)	23 Mar 2021 15:48:09

US3662116
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (11)
Generated On: 10 Jun 2021 09:24:58
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:39
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:14:54
User entered 'Adverse Event (AE)'	Angela Snyder (b) (4) (b) (4)	23 Mar 2021 15:48:09

US3662116
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (11)
Generated On: 10 Jun 2021 09:24:58
If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:39
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 16:14:54
User entered empty.	Angela Snyder (b) (4) (b) (4)	23 Mar 2021 15:48:09

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'USA-US088-2021-MRNA-1273-P301000009'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Serious

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'Yes (Y)'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Death

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'No (N)'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'No (N)'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'Yes (Y)'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'No (N)'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'No (N)'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'No (N)'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'Carl'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'Fichtenbaum'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered '231 Albert Sabin Way'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'Cincinnati'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered '45267'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:17:20
User entered 'US'	System	16 Feb 2021 14:47:12

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '5'	System	07 Apr 2021 13:57:20
User entered '4'	System	25 Mar 2021 15:29:43
User entered '3'	System	23 Feb 2021 21:21:30
User entered '2'	System	18 Feb 2021 14:17:34
User entered '1'	System	16 Feb 2021 14:47:12

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'USA-US088-2021-MRNA-1273-P301000009'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Serious

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'Yes (Y)'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Death

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'No (N)'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'No (N)'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'Yes (Y)'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'No (N)'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'No (N)'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'No (N)'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'Carl'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'Fichtenbaum'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered '231 Albert Sabin Way'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'Cincinnati'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered '45267'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:17:20
User entered 'US'	System	16 Feb 2021 14:47:12

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '5'	System	07 Apr 2021 13:57:20
User entered '4'	System	25 Mar 2021 15:29:43
User entered '3'	System	23 Feb 2021 21:21:30
User entered '2'	System	18 Feb 2021 14:17:34
User entered '1'	System	16 Feb 2021 14:47:12

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form (1)
Generated On: 10 Jun 2021 09:24:58
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
User entered '16/Feb/2021 09:47'	System	16 Feb 2021 14:47:12

US3662116

Folder: SAE USA-US088-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:24:58

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.

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:17:20
User entered '1'	(b) (4), (b) (6)	16 Feb 2021 14:47:12

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'USA-US088-2021-MRNA-1273-P301000009'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Serious

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'Yes (Y)'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Death

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'No (N)'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'No (N)'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'Yes (Y)'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'No (N)'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'No (N)'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'No (N)'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'Carl'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'Fichtenbaum'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered '231 Albert Sabin Way'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'Cincinnati'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered '45267'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:17:20
User entered 'US'	System	16 Feb 2021 14:47:12

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '5'	System	07 Apr 2021 13:57:20
User entered '4'	System	25 Mar 2021 15:29:43
User entered '3'	System	23 Feb 2021 21:21:30
User entered '2'	System	18 Feb 2021 14:17:34
User entered '1'	System	16 Feb 2021 14:47:12

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form (2)
Generated On: 10 Jun 2021 09:24:58
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
User entered '18/Feb/2021 14:17'	System	18 Feb 2021 14:17:34

US3662116

Folder: SAE USA-US088-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:24:58

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.

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 21:20:21
User entered '1'	(b) (4), (b) (6)	18 Feb 2021 14:17:34

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'USA-US088-2021-MRNA-1273-P301000009'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Serious

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'Yes (Y)'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Death

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'No (N)'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'No (N)'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'Yes (Y)'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'No (N)'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'No (N)'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'No (N)'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'Carl'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'Fichtenbaum'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered '231 Albert Sabin Way'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'Cincinnati'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered '45267'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:17:20
User entered 'US'	System	16 Feb 2021 14:47:12

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '5'	System	07 Apr 2021 13:57:20
User entered '4'	System	25 Mar 2021 15:29:43
User entered '3'	System	23 Feb 2021 21:21:30
User entered '2'	System	18 Feb 2021 14:17:34
User entered '1'	System	16 Feb 2021 14:47:12

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form (3)
Generated On: 10 Jun 2021 09:24:58
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
User entered '23/Feb/2021 15:21'	System	23 Feb 2021 21:21:30

US3662116

Folder: SAE USA-US088-2021-MRNA-1273-P301000009

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:24:58

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.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 13:57:10
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
User entered '1'	(b) (4), (b) (6)	23 Feb 2021 21:21:30

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'USA-US088-2021-MRNA-1273-P301000009'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Serious

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'Yes (Y)'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Death

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'No (N)'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'No (N)'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'Yes (Y)'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'No (N)'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'No (N)'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'No (N)'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'Carl'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'Fichtenbaum'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered '231 Albert Sabin Way'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'Cincinnati'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered '45267'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:17:20
User entered 'US'	System	16 Feb 2021 14:47:12

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '5'	System	07 Apr 2021 13:57:20
User entered '4'	System	25 Mar 2021 15:29:43
User entered '3'	System	23 Feb 2021 21:21:30
User entered '2'	System	18 Feb 2021 14:17:34
User entered '1'	System	16 Feb 2021 14:47:12

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form (4)
Generated On: 10 Jun 2021 09:24:58
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:41:18
User entered '25/Mar/2021 11:29'	System	25 Mar 2021 15:29:43

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form (4)
Generated On: 10 Jun 2021 09:24:58
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.

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	08 Apr 2021 21:54:54
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 13:57:10
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:41:18
User entered '1'	(b) (4), (b) (6)	25 Mar 2021 15:29:43

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'USA-US088-2021-MRNA-1273-P301000009'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Serious

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'Yes (Y)'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Death

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'No (N)'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'No (N)'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'Yes (Y)'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'No (N)'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'No (N)'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'No (N)'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'Carl'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'Fichtenbaum'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered '231 Albert Sabin Way'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered 'Cincinnati'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	16 Feb 2021 14:47:04
User entered '45267'	System	16 Feb 2021 14:46:48

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	18 Mar 2021 22:08:25
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 19:17:43
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 14:17:20
User entered 'US'	System	16 Feb 2021 14:47:12

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form
Generated On: 10 Jun 2021 09:24:58
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '5'	System	07 Apr 2021 13:57:20
User entered '4'	System	25 Mar 2021 15:29:43
User entered '3'	System	23 Feb 2021 21:21:30
User entered '2'	System	18 Feb 2021 14:17:34
User entered '1'	System	16 Feb 2021 14:47:12

US3662116
Folder: SAE USA-US088-2021-MRNA-1273-P301000009
Form: Safety Report Form (5)
Generated On: 10 Jun 2021 09:24:58
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:00:42
User entered '07/Apr/2021 08:57'	System	07 Apr 2021 13:57:20

US3662116

Folder: SAE USA-US088-2021-MRNA-1273-P301000009

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:24:58

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.

Audit	User	Time (GMT)
User signature succeeded.	Carl Fichtenbaum (b) (4) (b) (4)	08 Apr 2021 21:54:54
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 16:00:42
User entered '1'	(b) (4), (b) (6)	07 Apr 2021 13:57:20