US3752173 (Prod: Baptist Health Center for Clinical Research)

Generated By: KC Joubran

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US3752173
Form: Participant Creation
Data signed: (b) (4) **12 Feb 2021 18:41:00**
Generated On: 10 Jun 2021 09:45:09

Participant ID	US3752173

mRNA-1273-P301 Completion Guidelines

FDA-CBER-2022-1614-3171178

US3752173
Folder: Screening
Form: Visit Date
Data signed: (b) (4) **12 Feb 2021 18:41:01**
Generated On: 10 Jun 2021 09:45:09

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

FDA-CBER-2022-1614-3171179

US3752173
Folder: Screening
Form: Demographics
Data signed: (b) (4) **12 Feb 2021 18:41:01**
Generated On: 10 Jun 2021 09:45:09

Date of Birth (MMM yyyy)	(b) (6) 1942
Age	77
Age Units	YEARS
Age (Derived)	77
Sex	Female ☐
	Male ■
Ethnicity	Hispanic or Latino ☐
	Not Hispanic or Latino ■
	Not Reported ☐
	Unknown ☐
Race (Check All That Apply)	
White	False
Black	False
Asian	False
American Indian or Alaska Native	True
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify	
Unknown	False
Not reported	False

FDA-CBER-2022-1614-3171180

US3752173
Folder: Screening
Form: Enrollment
Data signed: (b) (4) **12 Feb 2021 18:41:01**
Generated On: 10 Jun 2021 09:45:09

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

FDA-CBER-2022-1614-3171181

US3752173
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Data signed: (b) (4) **12 Feb 2021 18:41:01**
Generated On: 10 Jun 2021 09:45:09

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

FDA-CBER-2022-1614-3171182

US3752173
Folder: Screening
Form: Medical History Summary
Data signed: (b) (4) **12 Feb 2021 18:41:01**
Generated On: 10 Jun 2021 09:45:09

Were any significant conditions reported?	Yes ■ No ☐

FDA-CBER-2022-1614-3171183

US3752173
Folder: Screening
Form: Medical History (1)
Data signed: (b) (4) **12 Feb 2021 18:41:01**
Generated On: 10 Jun 2021 09:45:09

Condition	CATARACTS
Start date (dd MMM yyyy)	UN UNK 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-2022-1614-3171184

US3752173
Folder: Screening
Form: Medical History (2)
Data signed: (b) (4) **12 Feb 2021 18:41:01**
Generated On: 10 Jun 2021 09:45:09

Condition	BILATERAL HEARING LOSS
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-3171185

US3752173
Folder: Screening
Form: Medical History (3)
Data signed: (b) (4) **12 Feb 2021 18:41:01**
Generated On: 10 Jun 2021 09:45:09

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN UNK 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)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-3171186

US3752173
Folder: Screening
Form: Medical History (4)
Data signed: (b) (4) **12 Feb 2021 18:41:01**
Generated On: 10 Jun 2021 09:45:09

Condition	MYOCARDIAL INFARCTION
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ■
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

FDA-CBER-2022-1614-3171187

US3752173
Folder: Screening
Form: Medical History (5)
Data signed: (b) (4) **12 Feb 2021 18:41:01**
Generated On: 10 Jun 2021 09:45:09

Condition	CHRONIC OBSTRUCTIVE PULMONARY DISEASE
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

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US3752173
Folder: Screening
Form: Medical History (6)
Data signed: (b) (4) **12 Feb 2021 18:41:01**
Generated On: 10 Jun 2021 09:45:09

Condition	CHOLECYSTECTOMY FOR CHOLECYSTITIS
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ■
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

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US3752173
Folder: Screening
Form: Medical History (7)
Data signed: (b) (4) **12 Feb 2021 18:41:01**
Generated On: 10 Jun 2021 09:45:09

Condition	GERD/REFLUX
Start date (dd MMM yyyy)	UN UNK 2002
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 2002
Start Year (derived)	2002
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-3171190

US3752173
Folder: Screening
Form: Medical History (8)
Data signed: (b) (4) **12 Feb 2021 18:41:01**
Generated On: 10 Jun 2021 09:45:09

Condition	GOUT (LOCATION UNKNOWN)
Start date (dd MMM yyyy)	UN UNK 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)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-3171191

US3752173
Folder: Screening
Form: Medical History (9)
Data signed: (b) (4) **12 Feb 2021 18:41:01**
Generated On: 10 Jun 2021 09:45:09

Condition	LOW BACK PAIN
Start date (dd MMM yyyy)	UN UNK 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)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

US3752173
Folder: Screening
Form: Medical History (10)
Data signed: (b) (4) **12 Feb 2021 18:41:01**
Generated On: 10 Jun 2021 09:45:09

Condition	BASAL CELL CANCER ON FACE
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☑
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	JAN 2019
Stop Year (derived)	2019

FDA-CBER-2022-1614-3171193

US3752173
Folder: Screening
Form: Medical History (11)
Data signed: (b) (4) **12 Feb 2021 18:41:01**
Generated On: 10 Jun 2021 09:45:09

Condition	PROSTATE ENLARGEMENT
Start date (dd MMM yyyy)	UN UNK 2004
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 2004
Start Year (derived)	2004
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-3171194

US3752173
Folder: Screening
Form: Medical History (12)
Data signed: (b) (4) **12 Feb 2021 18:41:01**
Generated On: 10 Jun 2021 09:45:09

Condition	ISLAND PETICOH TRANSPLANT LEFT HAND
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes ☐ No ■
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	True
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-3171195

US3752173
Folder: Screening
Form: Medical History (13)
Data signed: (b) (4) **12 Feb 2021 18:41:01**
Generated On: 10 Jun 2021 09:45:09

Condition	RECONSTRUCTIVE LEFT HAND SURGERY
Start date (dd MMM yyyy)	UN UNK 1979
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ■
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1979
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1979
Start Year (derived)	1979
Stop Month and Year (derived)	JAN 1979
Stop Year (derived)	1979

FDA-CBER-2022-1614-3171196

US3752173
Folder: Screening
Form: Medical History (14)
Data signed: (b) (4) **12 Feb 2021 18:41:01**
Generated On: 10 Jun 2021 09:45:09

Condition	CHOLECYSTITIS
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ■
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

FDA-CBER-2022-1614-3171197

US3752173
Folder: Screening
Form: Medical History (15)
Data signed: (b) (4) **12 Feb 2021 18:41:01**
Generated On: 10 Jun 2021 09:45:09

Condition	CORONARY ARTERY DISEASE
Start date (dd MMM yyyy)	UN DEC 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)	DEC 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-3171198

US3752173
Folder: Screening
Form: Medical History (16)
Data signed: (b) (4) **12 Feb 2021 18:41:01**
Generated On: 10 Jun 2021 09:45:09

Condition	CARDIOMYOPATHY
Start date (dd MMM yyyy)	UN UNK 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)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-3171199

US3752173
Folder: Screening
Form: Medical History (17)
Data signed: (b) (4) **12 Feb 2021 18:41:01**
Generated On: 10 Jun 2021 09:45:09

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

FDA-CBER-2022-1614-3171200

US3752173
Folder: Screening
Form: Medical History (18)
Data signed: (b) (4) **12 Feb 2021 18:41:01**
Generated On: 10 Jun 2021 09:45:09

Condition	CARDIAC CATHETERIZATION
Start date (dd MMM yyyy)	6 NOV 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ■
If No, please specify the stop date (dd MMM yyyy)	06 NOV 2015
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2015
Start Year (derived)	2015
Stop Month and Year (derived)	NOV 2015
Stop Year (derived)	2015

FDA-CBER-2022-1614-3171201

US3752173
Folder: Screening
Form: Vital Signs
Data signed: (b) (4) **12 Feb 2021 18:41:01**
Generated On: 10 Jun 2021 09:45:09

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	20 AUG 2020
Time of assessment *(00:00-23:59)*	10:15 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 10:15
Height *(xxx.x)*	70.0 in
Weight *(xxx.x)*	195.1 lb
BMI *(xxx.x)*	28.05247 kg/m^2
BMI units	KG/M2
Temperature *(xxx.x)*	ND - Not Done
Route of measurement	Oral ☐ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	ND - Not Done
Pulse units	BPM
Respiratory Rate *(xxx)*	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-3171202

US3752173
Folder: Screening
Form: Physical Examination
Data signed: (b) (4) **12 Feb 2021 18:41:01**
Generated On: 10 Jun 2021 09:45:09

Was the physical examination performed?	Yes ☑ No ☐
Date of examination *(dd MMM yyyy)*	20 AUG 2020

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

FDA-CBER-2022-1614-3171203

US3752173
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **12 Feb 2021 18:41:01**
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Occupational Risk	
Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)	Yes ☐ No ■
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)	Yes ☐ No ■
Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)	Yes ☐ No ■
Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)	Yes ☐ No ■
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)	Yes ☐ No ■
Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)	Yes ☐ No ■
Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)	Yes ☐ No ■
Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)	Yes ■ No ☐
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)	Yes ☐ No ■
Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)	Yes ☐ No ■
Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)	Yes ☐ No ■
Other	Yes ☐ No ■
Specify	
Location and Living Circumstances Risk (check all that apply)	
No Risk Identified	True
Resides in Nursing Home or Assisted Living Facility	False

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

US3752173
Folder: Visit 1 Day 1
Form: Visit Date
Data signed: (b) (4) **12 Feb 2021 18:41:01**
Generated On: 10 Jun 2021 09:45:09

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

FDA-CBER-2022-1614-3171206

US3752173
Folder: Visit 1 Day 1
Form: Randomization
Data signed: (b) (4) **12 Feb 2021 18:41:01**
Generated On: 10 Jun 2021 09:45:09

What was the date of randomization? *(dd MMM yyyy)*	20 AUG 2020
What was the participant's randomization number?	187144
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-2022-1614-3171207

US3752173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Data signed: (b) (4) **12 Feb 2021 18:41:01**
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Height	ND - Not Done
Weight	ND - Not Done

FDA-CBER-2022-1614-3171208

US3752173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **12 Feb 2021 18:41:01**
Generated On: 10 Jun 2021 09:45:09

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ■ Post-Dose ☐
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	20 AUG 2020
Time of assessment *(00:00-23:59)*	10:15 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 10:15
Temperature *(xxx.x)*	97.9 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	061 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	074 mmHg
Diastolic Blood Pressure units	MMHG

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US3752173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **12 Feb 2021 18:41:01**
Generated On: 10 Jun 2021 09:45:09

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ■
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	20 AUG 2020
Time of assessment *(00:00-23:59)*	11:20 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 11:20
Temperature *(xxx.x)*	98.7 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	60 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	70 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-3171210

US3752173
Folder: Visit 1 Day 1
Form: Physical Examination
Data signed: (b) (4) **12 Feb 2021 18:41:01**
Generated On: 10 Jun 2021 09:45:09

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-2022-1614-3171211

US3752173
Folder: Visit 1 Day 1
Form: Exposure
Data signed: (b) (4) **12 Feb 2021 18:41:01**
Generated On: 10 Jun 2021 09:45:09

Was study treatment given?	Yes ■ No ☐
If No, reason not given	Participant declined due to Adverse Event ☐ Physician withheld dose due to Adverse Event ☐ Death ☐ Lost To Follow-Up ☐ Physician Decision ☐ Pregnancy ☐ Protocol Deviation ☐ Study Terminated by Sponsor ☐ Withdrawal of Consent by Participant ☐ Confirmed COVID-19 ☐ Other ☐
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? *(dd MMM yyyy)*	20 AUG 2020
What was the treatment time? *(00:00-23:59)*	10:46 (24 HR)
Treatment Date and Time (derived)	20 AUG 2020 10:46
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-2022-1614-3171212

US3752173
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Data signed: (b) (4) **12 Feb 2021 18:41:01**
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Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	20 AUG 2020
Collection time *(00:00-23:59)*	10:29 (24 HR)
Collection date and time (derived)	20 AUG 2020 10:29

FDA-CBER-2022-1614-3171213

US3752173
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **12 Feb 2021 18:41:01**
Generated On: 10 Jun 2021 09:45:09

Collection date *(dd MMM yyyy)*			20 AUG 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:27	20 AUG 2020 10:27
Nasopharyngeal Swab 2	No		

FDA-CBER-2022-1614-3171214

US3752173
Folder: Visit 1 Day 1
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 18:41:01**
Generated On: 10 Jun 2021 09:45:09

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

FDA-CBER-2022-1614-3171215

US3752173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:45:09

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**	98.7 °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	20 AUG 2020 11:24
PC Open Date & Time	20 AUG 2020 11:06
PC Close Date & Time	20 AUG 2020 13:36

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US3752173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:45:09

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**	98.2 °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 AUG 2020 18:23
PC Open Date & Time	20 AUG 2020 14:31
PC Close Date & Time	21 AUG 2020 11:59

FDA-CBER-2022-1614-3171217

US3752173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:45:09

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**	94.2 °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	21 AUG 2020 20:38
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3752173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:45:09

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**	98.0 °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 AUG 2020 19:35
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

FDA-CBER-2022-1614-3171219

US3752173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:45:09

TIMEPOINT	DAY 4

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.2 °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 AUG 2020 21:23
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3752173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:45:09

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**	97.4 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	24 AUG 2020 20:35
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

FDA-CBER-2022-1614-3171221

US3752173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:45:09

TIMEPOINT	DAY 6

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.6 °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	25 AUG 2020 20:06
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

FDA-CBER-2022-1614-3171222

US3752173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:45:09

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**	97.7 °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	26 AUG 2020 19:19
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

FDA-CBER-2022-1614-3171223

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:45:09

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	20 AUG 2020 11:25
PC Open Date & Time	20 AUG 2020 11:06
PC Close Date & Time	20 AUG 2020 13:36

FDA-CBER-2022-1614-3171224

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:45:09

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	20 AUG 2020 18:24
PC Open Date & Time	20 AUG 2020 14:31
PC Close Date & Time	21 AUG 2020 11:59

FDA-CBER-2022-1614-3171225

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:45:09

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	21 AUG 2020 20:39
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

FDA-CBER-2022-1614-3171226

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:45:09

TIMEPOINT	DAY 3
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ☐ Does not interfere with activity ■ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	22 AUG 2020 19:36
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

FDA-CBER-2022-1614-3171227

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:45:09

TIMEPOINT	DAY 4
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ● Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ●
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ●
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ● Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	23 AUG 2020 21:24
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

FDA-CBER-2022-1614-3171228

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:45:09

TIMEPOINT	DAY 5
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ● Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ●
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ●
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ● Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	24 AUG 2020 20:36
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

FDA-CBER-2022-1614-3171229

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:45:09

TIMEPOINT	DAY 6
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	25 AUG 2020 20:07
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:45:09

TIMEPOINT	DAY 7
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ■
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ■ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	26 AUG 2020 19:20
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:45:09

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-2022-1614-3171232

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:45:09

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☑ Yes ☐
PC Time stamp	20 AUG 2020 11:26
PC Open Date & Time	20 AUG 2020 11:06
PC Close Date & Time	20 AUG 2020 13:36

FDA-CBER-2022-1614-3171233

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-2022-1614-3171234

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:45:09

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	20 AUG 2020 18:25
PC Open Date & Time	20 AUG 2020 14:31
PC Close Date & Time	21 AUG 2020 11:59

FDA-CBER-2022-1614-3171235

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:45:09

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-2022-1614-3171236

	Yes ☐
PC Time stamp	21 AUG 2020 20:40
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:45:09

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-2022-1614-3171238

	Yes ☐
PC Time stamp	22 AUG 2020 19:37
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:45:09

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-2022-1614-3171240

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:45:09

	Yes ☐
PC Time stamp	23 AUG 2020 21:25
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

FDA-CBER-2022-1614-3171241

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:45:09

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-2022-1614-3171242

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:45:09

	Yes ☐
PC Time stamp	24 AUG 2020 20:38
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

FDA-CBER-2022-1614-3171243

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:45:09

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-2022-1614-3171244

	Yes ☐
PC Time stamp	25 AUG 2020 20:08
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:45:09

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-2022-1614-3171246

	Yes ☐
PC Time stamp	26 AUG 2020 19:21
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3752173
Folder: Safety Call Day 8 (1)
Form: Safety Call
Data signed: (b) (4) **12 Feb 2021 18:41:01**
Generated On: 10 Jun 2021 09:45:09

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

FDA-CBER-2022-1614-3171248

US3752173
Folder: Safety Call Day 8 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 18:41:01**
Generated On: 10 Jun 2021 09:45:09

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

FDA-CBER-2022-1614-3171249

US3752173
Folder: Safety Call Day 15 (1)
Form: Safety Call
Data signed: (b) (4) **12 Feb 2021 18:41:00**
Generated On: 10 Jun 2021 09:45:09

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	4 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-2022-1614-3171250

US3752173
Folder: Safety Call Day 15 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 18:41:00**
Generated On: 10 Jun 2021 09:45:09

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

FDA-CBER-2022-1614-3171251

US3752173
Folder: Safety Call Day 22 (1)
Form: Safety Call
Data signed: (b) (4) **12 Feb 2021 18:41:00**
Generated On: 10 Jun 2021 09:45:09

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	11 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-2022-1614-3171252

US3752173
Folder: Safety Call Day 22 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 18:41:00**
Generated On: 10 Jun 2021 09:45:09

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

FDA-CBER-2022-1614-3171253

US3752173
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Data signed: (b) (4) **12 Feb 2021 18:41:01**
Generated On: 10 Jun 2021 09:45:09

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	VISIT2

FDA-CBER-2022-1614-3171254

US3752173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **12 Feb 2021 18:41:01**
Generated On: 10 Jun 2021 09:45:09

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)*	10:10 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 10:10
Temperature *(xxx.x)*	98.0 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	64 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	70 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-3171255

US3752173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **12 Feb 2021 18:41:01**
Generated On: 10 Jun 2021 09:45:09

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)*	11:20 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 11:20
Temperature *(xxx.x)*	98.0 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	66 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	62 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-3171256

US3752173
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Data signed: (b) (4) **12 Feb 2021 18:41:01**
Generated On: 10 Jun 2021 09:45:09

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-2022-1614-3171257

US3752173
Folder: Visit 2 Day 29 (1)
Form: Exposure
Data signed: (b) (4) **12 Feb 2021 18:41:01**
Generated On: 10 Jun 2021 09:45:09

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)*	11:00 (24 HR)
Treatment Date and Time (derived)	18 SEP 2020 11:00
Which arm was used to give treatment?	Left Arm ■ Right Arm ☐
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

FDA-CBER-2022-1614-3171258

US3752173
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **12 Feb 2021 18:41:01**
Generated On: 10 Jun 2021 09:45:09

Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	18 SEP 2020
Collection time *(00:00-23:59)*	10:25 (24 HR)
Collection date and time (derived)	18 SEP 2020 10:25

US3752173
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **12 Feb 2021 18:41:01**
Generated On: 10 Jun 2021 09:45:09

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	10:23	18 SEP 2020 10:23
Nasopharyngeal Swab 2	No		

FDA-CBER-2022-1614-3171260

US3752173
Folder: Visit 2 Day 29 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 18:41:01**
Generated On: 10 Jun 2021 09:45:09

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

FDA-CBER-2022-1614-3171261

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:45:09

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 11:30
PC Open Date & Time	18 SEP 2020 11:20
PC Close Date & Time	18 SEP 2020 13:50

FDA-CBER-2022-1614-3171262

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:45:09

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**	97.5 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	18 SEP 2020 19:37
PC Open Date & Time	18 SEP 2020 14:45
PC Close Date & Time	19 SEP 2020 11:59

FDA-CBER-2022-1614-3171263

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:45:09

TIMEPOINT	DAY 2

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	99.7 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	19 SEP 2020 19:20
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:45:09

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**	98.3 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	20 SEP 2020 19:18
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:45:09

TIMEPOINT	DAY 4

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

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

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

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

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

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

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

FDA-CBER-2022-1614-3171266

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:45:09

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

FDA-CBER-2022-1614-3171267

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:45:09

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

FDA-CBER-2022-1614-3171268

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:45:09

TIMEPOINT	DAY 7

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ☐ No ☐
Please record your **TEMPERATURE in °F**	
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	
To **PREVENT** pain or fever from occurring	
PC Time Stamp	
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

FDA-CBER-2022-1614-3171269

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:45:09

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 11:31
PC Open Date & Time	18 SEP 2020 11:20
PC Close Date & Time	18 SEP 2020 13:50

FDA-CBER-2022-1614-3171270

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:45:09

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 19:33
PC Open Date & Time	18 SEP 2020 14:45
PC Close Date & Time	19 SEP 2020 11:59

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:45:09

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 19:21
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:45:09

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 19:18
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:45:09

TIMEPOINT	DAY 4
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ☐ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ☐
Please record - **REDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site redness with the ruler provided.	
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ☐
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site swelling/hardness with the ruler provided.	
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ☐ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

FDA-CBER-2022-1614-3171274

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:45:09

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 ☐
Please record - **REDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site redness with the ruler provided.	
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ☐
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site swelling/hardness with the ruler provided.	
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ☐ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

FDA-CBER-2022-1614-3171275

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:45:09

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 ☐
Please record - **REDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site redness with the ruler provided.	
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ☐
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site swelling/hardness with the ruler provided.	
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ☐ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

FDA-CBER-2022-1614-3171276

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:45:09

TIMEPOINT	DAY 7
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ☐ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ☐
Please record - **REDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site redness with the ruler provided.	
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ☐
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site swelling/hardness with the ruler provided.	
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ☐ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

FDA-CBER-2022-1614-3171277

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:45:09

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-2022-1614-3171278

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:45:09

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☑ Yes ☐
PC Time stamp	18 SEP 2020 11:32
PC Open Date & Time	18 SEP 2020 11:20
PC Close Date & Time	18 SEP 2020 13:50

FDA-CBER-2022-1614-3171279

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-2022-1614-3171280

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:45:09

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	18 SEP 2020 19:38
PC Open Date & Time	18 SEP 2020 14:45
PC Close Date & Time	19 SEP 2020 11:59

FDA-CBER-2022-1614-3171281

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:45:09

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-2022-1614-3171282

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:45:09

	Yes ☐
PC Time stamp	19 SEP 2020 19:23
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

FDA-CBER-2022-1614-3171283

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:45:09

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-2022-1614-3171284

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:45:09

	Yes ☐
PC Time stamp	20 SEP 2020 19:19
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:45:09

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-2022-1614-3171286

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

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:45:09

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-2022-1614-3171288

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:45:09

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

FDA-CBER-2022-1614-3171289

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-2022-1614-3171290

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

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-2022-1614-3171292

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

US3752173
Folder: Safety Call Day 36 (1)
Form: Safety Call
Data signed: (b) (4) **12 Feb 2021 18:41:00**
Generated On: 10 Jun 2021 09:45:09

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-2022-1614-3171294

US3752173
Folder: Safety Call Day 36 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 18:41:00**
Generated On: 10 Jun 2021 09:45:09

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

FDA-CBER-2022-1614-3171295

US3752173
Folder: Safety Call Day 43 (1)
Form: Safety Call
Data signed: (b) (4) **12 Feb 2021 18:41:00**
Generated On: 10 Jun 2021 09:45:09

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	2 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-2022-1614-3171296

US3752173
Folder: Safety Call Day 43 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 18:41:00**
Generated On: 10 Jun 2021 09:45:09

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

FDA-CBER-2022-1614-3171297

US3752173
Folder: Safety Call Day 50 (1)
Form: Safety Call
Data signed: (b) (4) **12 Feb 2021 18:41:01**
Generated On: 10 Jun 2021 09:45:09

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	9 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-2022-1614-3171298

US3752173
Folder: Safety Call Day 50 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 18:41:01**
Generated On: 10 Jun 2021 09:45:09

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

FDA-CBER-2022-1614-3171299

US3752173
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Data signed: (b) (4) **12 Feb 2021 18:41:01**
Generated On: 10 Jun 2021 09:45:09

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	23 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT3

FDA-CBER-2022-1614-3171300

US3752173
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Data signed: (b) (4) **12 Feb 2021 18:41:01**
Generated On: 10 Jun 2021 09:45:09

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	23 OCT 2020
Time of assessment *(00:00-23:59)*	10:35 (24 HR)
Vital Signs Date and Time (derived)	23 OCT 2020 10:35
Temperature *(xxx.x)*	97.2 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	68 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	58 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3752173
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Data signed: (b) (4) **12 Feb 2021 18:41:01**
Generated On: 10 Jun 2021 09:45:09

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	23 OCT 2020

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

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US3752173
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **12 Feb 2021 18:41:01**
Generated On: 10 Jun 2021 09:45:09

Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	23 OCT 2020
Collection time *(00:00-23:59)*	10:45 (24 HR)
Collection date and time (derived)	23 OCT 2020 10:45

US3752173
Folder: Visit 3 Day 57 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 18:41:01**
Generated On: 10 Jun 2021 09:45:09

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

FDA-CBER-2022-1614-3171304

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

US3752173
Folder: Safety Call Day 85 (1)
Form: Safety Call
Data signed: (b) (4) **23 Apr 2021 14:51:23**
Generated On: 10 Jun 2021 09:45:09

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-2022-1614-3171306

US3752173
Folder: Safety Call Day 85 (1)
Form: Continuing
Data signed: (b) (4) **22 Apr 2021 15:22:09**
Generated On: 10 Jun 2021 09:45:09

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

FDA-CBER-2022-1614-3171307

US3752173
Folder: Safety Call Day 119 (1)
Form: Safety Call
Data signed: (b) (4) **12 Feb 2021 18:41:00**
Generated On: 10 Jun 2021 09:45:09

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*	EARLY TERMINATION DUE TO DEATH

FDA-CBER-2022-1614-3171308

US3752173
Folder: Safety Call Day 119 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 18:41:00**
Generated On: 10 Jun 2021 09:45:09

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

FDA-CBER-2022-1614-3171309

US3752173
Folder: Covid-19 Assessment (1)
Form: COVID-19 Contact
Data signed: (b) (4) **12 Feb 2021 18:41:00**
Generated On: 10 Jun 2021 09:45:09

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-2022-1614-3171310

US3752173
Folder: Covid-19 Assessment (1)
Form: Generate Next COVID-19 Assessment
Data signed: (b) (4) **12 Feb 2021 18:41:00**
Generated On: 10 Jun 2021 09:45:09

Generate Next COVID-19 Assessment	Yes ☐ No ■

FDA-CBER-2022-1614-3171311

US3752173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:45:09

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

FDA-CBER-2022-1614-3171312

US3752173
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:45:09

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

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

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

US3752173
Folder: Adverse Events
Form: Adverse Events Summary
Data signed: (b) (4) **12 Feb 2021 18:41:00**
Generated On: 10 Jun 2021 09:45:09

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

If Yes, enter details on the Adverse Events form.

FDA-CBER-2022-1614-3171316

US3752173
Folder: Adverse Events
Form: Adverse Events (1)
Data signed: (b) (4) **12 Feb 2021 18:41:00**
Generated On: 10 Jun 2021 09:45:09

AEID	USA-US113-2020-MRNA-1273-P301000007
Adverse event	MYOCARDIAL INFARCTION
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)*	01 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)*	01 NOV 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ■
Is the adverse event serious?	Yes ■ No ☐
AE is serious due To (check all that apply)	
Death	True
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 ☐

FDA-CBER-2022-1614-3171317

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ■ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ■ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ■
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ■ Not Recovered/Not Resolved ☐ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUBJECT'S DAUGHTER CALLED THE SITE ON 02 NOV 2020 AT 8:00 AND TO REPORT THAT THE SUBJECT HAD DIED OF A "MASSIVE HEART ATTACK" ON 01 NOV 2020
Serious Adverse Event Derived (CSA Programming Field Ony)	1

FDA-CBER-2022-1614-3171318

US3752173
Folder: Adverse Events
Form: Adverse Events (1)
Data signed: (b) (4) **12 Feb 2021 18:41:00**
Generated On: 10 Jun 2021 09:45:09

Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

FDA-CBER-2022-1614-3171319

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Data signed: (b) (4) **12 Feb 2021 18:41:00**
Generated On: 10 Jun 2021 09:45:09

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

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

FDA-CBER-2022-1614-3171320

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Data signed: (b) (4) **12 Feb 2021 18:41:00**
Generated On: 10 Jun 2021 09:45:09

Name of Medication	FISH OIL
Prophylaxis	Yes ■ No ☐
Indication	PROPHYLAXIS FOR CARDIAC DISEASE
Dose per administration	1200
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐

FDA-CBER-2022-1614-3171321

	Intraocular ☐
	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN MAY 2005
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	01 NOV 2020
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Data signed: (b) (4) **12 Feb 2021 18:41:00**
Generated On: 10 Jun 2021 09:45:09

Name of Medication	OMEPRAZOLE
Prophylaxis	Yes ☐
	No ■
Indication	GERD
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-2022-1614-3171323

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN JAN 2010
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	01 NOV 2020
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Data signed: (b) (4) **12 Feb 2021 18:41:00**
Generated On: 10 Jun 2021 09:45:09

Name of Medication	ASPIRIN
Prophylaxis	Yes ■ No ☐
Indication	PROPHYLAXIS FOR CARDIAC DISEASE
Dose per administration	81
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-2022-1614-3171325

	Intraocular ☐
	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN JUN 2015
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	01 NOV 2020
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Data signed: (b) (4) **12 Feb 2021 18:41:00**
Generated On: 10 Jun 2021 09:45:09

Name of Medication	CARVEDILOL
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 ☐

FDA-CBER-2022-1614-3171327

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN JUN 2015
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	01 NOV 2020
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Data signed: (b) (4) **12 Feb 2021 18:41:00**
Generated On: 10 Jun 2021 09:45:09

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

FDA-CBER-2022-1614-3171329

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN JUN 2015
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	01 NOV 2020
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Data signed: (b) (4) **12 Feb 2021 18:41:00**
Generated On: 10 Jun 2021 09:45:09

Name of Medication	SYMBICORT
Prophylaxis	Yes ☐ No ■
Indication	CHRONIC OBSTRUCTIVE PULMONARY DISEASE
Dose per administration	160/4.5
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ■ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐

FDA-CBER-2022-1614-3171331

	Intraocular ☐ Intramuscular ☐ Respiratory (Inhalation) ■ Intralesional ☐ Intraperiteoneal ☐ Nasal ☐ Vaginal ☐ Rectal ☐ Intravenous ☐ Intravenous Bolus ☐ Intravenous Drip ☐ Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN JUN 2015
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	01 NOV 2020
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Data signed: (b) (4) **12 Feb 2021 18:41:00**
Generated On: 10 Jun 2021 09:45:09

Name of Medication	FLUTICASONE
Prophylaxis	Yes ☐ No ■
Indication	CHRONIC OBSTRUCTIVE PULMONARY DISEASE
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)*	UN JUN 2015
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	01 NOV 2020
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Data signed: (b) (4) **12 Feb 2021 18:41:00**
Generated On: 10 Jun 2021 09:45:09

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

FDA-CBER-2022-1614-3171335

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN JUL 2018
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	01 NOV 2020
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Data signed: (b) (4) **12 Feb 2021 18:41:00**
Generated On: 10 Jun 2021 09:45:09

Name of Medication	TAMSULOSIN
Prophylaxis	Yes ☐ No ■
Indication	ENLARGED PROSTATE
Dose per administration	0.045
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	UNKNOWN
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

FDA-CBER-2022-1614-3171337

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN AUG 2019
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	01 NOV 2020
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Data signed: (b) (4) **12 Feb 2021 18:41:00**
Generated On: 10 Jun 2021 09:45:09

Name of Medication	ALBUTEROL
Prophylaxis	Yes ☐ No ■
Indication	CHRONIC OBSTRUCTIVE PULMONARY DISEASE
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 ☐ Intramuscular ☐ Respiratory (Inhalation) ■ Intralesional ☐ Intraperiteoneal ☐ Nasal ☐ Vaginal ☐ Rectal ☐ Intravenous ☐ Intravenous Bolus ☐ Intravenous Drip ☐ Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN JAN 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	01 NOV 2020
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Data signed: (b) (4) **12 Feb 2021 18:41:00**
Generated On: 10 Jun 2021 09:45:09

Name of Medication	MUCINEX
Prophylaxis	Yes ☐ No ■
Indication	CHRONIC OBSTRUCTIVE PULMONARY DISEASE
Dose per administration	1200
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐

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	Intraocular ☐
	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN JAN 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	01 NOV 2020
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

Name of Medication	MULTIVITAMIN
Prophylaxis	Yes ■ No ☐
Indication	SUPPLEMENT
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ■ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN FEB 2019
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	01 NOV 2020
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Data signed: (b) (4) **12 Feb 2021 18:41:00**
Generated On: 10 Jun 2021 09:45:09

Name of Medication	SEASONAL INFLUENZA VACCINE
Prophylaxis	Yes ■ No ☐
Indication	PROPHYLAXIS FOR SEASONAL INFLUENZA
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 ☐

FDA-CBER-2022-1614-3171345

	Intraocular ☐
	Intramuscular ■
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	20 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	20 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 ☐

US3752173
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Data signed: (b) (4) **12 Feb 2021 18:41:00**
Generated On: 10 Jun 2021 09:45:09

Were any concomitant procedures performed?	Yes ☐
	No ■

If yes, please complete Concomitant Procedures form.

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US3752173
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Data signed: (b) (4) **20 Mar 2021 01:29:27**
Generated On: 10 Jun 2021 09:45:09

Date of study discontinuation/completion *(dd MMM yyyy)*	01 NOV 2020
Reason for discontinuation	AE (specify) ☐ SAE (specify) ☐ Complete ☐ Death ■ Lost To Follow-up ☐ Physician decision (specify) ☐ Pregnancy ☐ Protocol deviation (specify) ☐ Study Terminated By Sponsor ☐ Withdrawal of consent by participant (specify) ☐ Other ☐
If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify	
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)*	01 NOV 2020
Was autopsy performed?	Yes ☐ No ■ Unknown ☐

FDA-CBER-2022-1614-3171348

US3752173
Folder: SAE USA-US113-2020-MRNA-1273-P301000007
Form: Safety Report Form
Data signed: (b) (4) **12 Feb 2021 18:41:00**
Generated On: 10 Jun 2021 09:45:09

SAEID	USA-US113-2020-MRNA-1273-P301000007
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	PRIYANTHA
Investigator's Last Name	WIJEWARDANE
Site Address: Street	9601 BAPTIST HEALTH DRIVE,SUITE 310
Site Address: City	LITTLE ROCK
Site Address: State	ARKANSAS
Site Address: Postal Code	72022
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3752173
Folder: SAE USA-US113-2020-MRNA-1273-P301000007
Form: Safety Report Form (1)
Data signed: (b) (4) **12 Feb 2021 18:41:00**
Generated On: 10 Jun 2021 09:45:09

SAEID	USA-US113-2020-MRNA-1273-P301000007
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	PRIYANTHA
Investigator's Last Name	WIJEWARDANE
Site Address: Street	9601 BAPTIST HEALTH DRIVE,SUITE 310
Site Address: City	LITTLE ROCK
Site Address: State	ARKANSAS
Site Address: Postal Code	72022
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	03/NOV/2020 08:09
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

US3752173 (Prod: Baptist Health Center for Clinical Research)

US3752173
Form: Participant Creation
Generated On: 10 Jun 2021 09:45:09
Participant ID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'US3752173'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 15:09:50

FDA-CBER-2022-1614-3171352

US3752173
Form: Participant Creation
Generated On: 10 Jun 2021 09:45:09

mRNA-1273-P301 Completion Guidelines

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29

FDA-CBER-2022-1614-3171353

US3752173
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 09:45:09
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 15:56:37

US3752173
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 09:45:09
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User entered '20 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 15:09:51

FDA-CBER-2022-1614-3171355

US3752173
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 09:45:09
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	20 Aug 2020 15:56:37

US3752173
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 09:45:09
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered 'SCRN'	System	20 Aug 2020 15:56:37

FDA-CBER-2022-1614-3171357

US3752173
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:45:09
Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered (b) (6) 1942'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 15:09:53

FDA-CBER-2022-1614-3171358

US3752173
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:45:09
Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '77'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:52:41

US3752173
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:45:09
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered 'YEARS'	System	20 Aug 2020 19:52:41

US3752173
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:45:09
Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered '77'	System	20 Aug 2020 15:57:08

FDA-CBER-2022-1614-3171361

US3752173
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:45:09
Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'Male (M)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 20:04:35
User entered 'Female (F)'	(b) (4), (b) (6)	20 Aug 2020 19:52:41

US3752173
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:45:09
Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:52:41

US3752173
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:45:09
White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:52:41

US3752173
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:45:09
Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:52:41

US3752173
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:45:09
Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:52:41

US3752173
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:45:09
American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '1'	(b) (4), (b) (6)	20 Aug 2020 19:52:41

US3752173
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:45:09
Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:52:41

US3752173
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:45:09
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:52:41

US3752173
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:45:09
If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:52:41

US3752173
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:45:09
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:52:41

US3752173
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:45:09
Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:52:41

US3752173
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:45:09
Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '20 Aug 2020'	(b) (4), (b) (6)	20 Aug 2020 15:57:08

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US3752173
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:45:09
Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered 'Aug 2020'	System	20 Aug 2020 15:57:08

US3752173
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:45:09
Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered '2020'	System	20 Aug 2020 15:57:08

FDA-CBER-2022-1614-3171375

US3752173
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:45:09
Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'Amendment 2 (2)'	(b) (4), (b) (6)	20 Aug 2020 15:57:08

US3752173
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:45:09
Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 15:57:08

US3752173
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:45:09
If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 15:57:08

US3752173
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:45:09
If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 15:57:08

US3752173
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:45:09
Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 15:57:08

US3752173
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:45:09
If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 15:09:51

US3752173
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:45:09
Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered '1'	System	20 Aug 2020 15:57:18

FDA-CBER-2022-1614-3171382

US3752173
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Generated On: 10 Jun 2021 09:45:09
Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 15:57:18

US3752173
Folder: Screening
Form: Medical History Summary
Generated On: 10 Jun 2021 09:45:09
Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:06:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 19:52:59

US3752173
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:45:09
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Cataracts - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 19:55:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 19:55:20
Data point term sent to Coder	System	20 Aug 2020 19:53:48
User entered 'Cataracts'	(b) (4), (b) (6)	20 Aug 2020 19:53:18

US3752173
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:45:09
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'un UNK 2019'	(b) (4), (b) (6)	20 Aug 2020 19:53:18

US3752173
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:45:09
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:53:18

FDA-CBER-2022-1614-3171387

US3752173
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:45:09
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:53:18

US3752173
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:45:09
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:53:18

US3752173
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:45:09
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:53:18

US3752173
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:45:09
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered 'Jan 2019'	System	20 Aug 2020 19:53:18

FDA-CBER-2022-1614-3171391

US3752173
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:45:09
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered '2019'	System	20 Aug 2020 19:53:18

FDA-CBER-2022-1614-3171392

US3752173
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:45:09
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered empty.	System	20 Aug 2020 19:53:18

FDA-CBER-2022-1614-3171393

US3752173
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:45:09
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered empty.	System	20 Aug 2020 19:53:18

FDA-CBER-2022-1614-3171394

US3752173
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:45:09
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Hearing disorders, HLT: Hearing losses, PT: Deafness bilateral, LLT: Hearing loss bilateral - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 19:55:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 19:55:21
Data point term sent to Coder	System	20 Aug 2020 19:53:49
User entered 'Bilateral hearing loss'	(b) (4), (b) (6)	20 Aug 2020 19:53:42

US3752173
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:45:09
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'un UNK 2005'	(b) (4), (b) (6)	20 Aug 2020 19:53:42

FDA-CBER-2022-1614-3171396

US3752173
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:45:09
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:53:42

US3752173
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:45:09
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 19:53:42

US3752173
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:45:09
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:53:42

US3752173
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:45:09
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:53:42

US3752173
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:45:09
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered 'Jan 2005'	System	20 Aug 2020 19:53:42

FDA-CBER-2022-1614-3171401

US3752173
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:45:09
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered '2005'	System	20 Aug 2020 19:53:42

FDA-CBER-2022-1614-3171402

US3752173
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:45:09
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered empty.	System	20 Aug 2020 19:53:42

FDA-CBER-2022-1614-3171403

US3752173
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:45:09
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered empty.	System	20 Aug 2020 19:53:42

FDA-CBER-2022-1614-3171404

US3752173
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:45:09
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 19:55:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 19:55:58
Data point term sent to Coder	System	20 Aug 2020 19:54:50
User entered 'Hypercholesterolemia'	(b) (4), (b) (6)	20 Aug 2020 19:54:02

FDA-CBER-2022-1614-3171405

US3752173
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:45:09
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'un UNK 2015'	(b) (4), (b) (6)	20 Aug 2020 19:54:02

US3752173
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:45:09
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:54:02

US3752173
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:45:09
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 19:54:02

US3752173
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:45:09
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:54:02

US3752173
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:45:09
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:54:02

US3752173
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:45:09
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered 'Jan 2015'	System	20 Aug 2020 19:54:02

FDA-CBER-2022-1614-3171411

US3752173
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:45:09
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered '2015'	System	20 Aug 2020 19:54:02

FDA-CBER-2022-1614-3171412

US3752173
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:45:09
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered empty.	System	20 Aug 2020 19:54:02

FDA-CBER-2022-1614-3171413

US3752173
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:45:09
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered empty.	System	20 Aug 2020 19:54:02

FDA-CBER-2022-1614-3171414

US3752173
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:45:09
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User closed query 'Per CDM CR: Please review the status of this MH as the duration is unexpected for this acute medical condition. The effects of Myocardial Infarction may be ongoing but the event itself is not. Please correct dates or provide explanation for the Med History duration. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 19:16:45
Query 'Per CDM CR: Please review the status of this MH as the duration is unexpected for this acute medical condition. The effects of Myocardial Infarction may be ongoing but the event itself is not. Please correct dates or provide explanation for the Med History duration. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 13:07:48
User opened query 'Per CDM CR: Please review the status of this MH as the duration is unexpected for this acute medical condition. The effects of Myocardial Infarction may be ongoing but the event itself is not. Please correct dates or provide explanation for the Med History duration. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 23:21:56
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Myocardial infarction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 19:55:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 19:55:22
Data point term sent to Coder	System	20 Aug 2020 19:54:50
User entered 'Myocardial infarction'	(b) (4), (b) (6)	20 Aug 2020 19:54:34

US3752173
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:45:09
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'un UNK 2015'	(b) (4), (b) (6)	20 Aug 2020 19:54:34

US3752173
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:45:09
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:54:34

US3752173
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:45:09
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
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	13 Oct 2020 13:07:38
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	13 Oct 2020 13:07:25
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Oct 2020 13:07:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 19:54:34

US3752173
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:45:09
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'un UNK 2015' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	13 Oct 2020 13:07:38
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 19:54:34

FDA-CBER-2022-1614-3171419

US3752173
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:45:09
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:54:34

US3752173
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:45:09
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered 'Jan 2015'	System	20 Aug 2020 19:54:34

FDA-CBER-2022-1614-3171421

US3752173
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:45:09
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered '2015'	System	20 Aug 2020 19:54:34

FDA-CBER-2022-1614-3171422

US3752173
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:45:09
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered 'Jan 2015'	System	13 Oct 2020 13:07:38
User entered empty.	System	20 Aug 2020 19:54:34

FDA-CBER-2022-1614-3171423

US3752173
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:45:09
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered '2015'	System	13 Oct 2020 13:07:38
User entered empty.	System	20 Aug 2020 19:54:34

FDA-CBER-2022-1614-3171424

US3752173
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 09:45:09
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User closed query 'Per MM, please expand the abbrevation ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:41:45
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: Chronic obstructive pulmonary disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Oct 2020 15:20:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Oct 2020 15:20:25
Query 'Per MM, please expand the abbrevation ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 15:18:55
Data point term sent to Coder	System	05 Oct 2020 15:18:53
Coding entries removed.	(b) (4), (b) (6)	05 Oct 2020 15:18:50
User entered 'Chronic obstructive pulmonary disease' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Oct 2020 15:18:50
User opened query 'Per MM, please expand the abbrevation ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 02:34:14
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: COPD - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 19:57:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 19:57:31
Data point term sent to Coder	System	20 Aug 2020 19:55:52
User entered 'COPD'	(b) (4), (b) (6)	20 Aug 2020 19:54:57

US3752173
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 09:45:09
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'un UNK 2005'	(b) (4), (b) (6)	20 Aug 2020 19:54:57

US3752173
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 09:45:09
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:54:57

US3752173
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 09:45:09
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 19:54:57

FDA-CBER-2022-1614-3171428

US3752173
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 09:45:09
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:54:57

US3752173
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 09:45:09
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:54:57

US3752173
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 09:45:09
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered 'Jan 2005'	System	20 Aug 2020 19:54:57

FDA-CBER-2022-1614-3171431

US3752173
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 09:45:09
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered '2005'	System	20 Aug 2020 19:54:57

FDA-CBER-2022-1614-3171432

US3752173
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 09:45:09
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered empty.	System	20 Aug 2020 19:54:57

FDA-CBER-2022-1614-3171433

US3752173
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 09:45:09
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered empty.	System	20 Aug 2020 19:54:57

FDA-CBER-2022-1614-3171434

US3752173
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 09:45:09
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 19:16:55
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)	17 Oct 2020 09:53:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Oct 2020 09:53:54
Data point term sent to Coder	System	16 Oct 2020 16:21:26
User entered 'CHOLECYSTECTOMY for cholecystitis' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 16:20:29
Data point term sent to Coder	System	16 Oct 2020 16:20:25
Coding entries removed.	(b) (4), (b) (6)	16 Oct 2020 16:19:35
User entered 'CHOLECYSTECTOMY (unknown associated condition)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 16:19:35
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 13:14:17
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 23:22:40
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)	20 Aug 2020 19:57:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 19:57:32

US3752173
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 09:45:09
Condition

Audit	User	Time (GMT)
Data point term sent to Coder	System	20 Aug 2020 19:55:54
User entered 'Cholecystectomy'	(b) (4), (b) (6)	20 Aug 2020 19:55:23

FDA-CBER-2022-1614-3171436

US3752173
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 09:45:09
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'un UNK 2015'	(b) (4), (b) (6)	20 Aug 2020 19:55:23

FDA-CBER-2022-1614-3171437

US3752173
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 09:45:09
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:55:23

FDA-CBER-2022-1614-3171438

US3752173
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 09:45:09
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 19:55:23

FDA-CBER-2022-1614-3171439

US3752173
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 09:45:09
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'un UNK 2015'	(b) (4), (b) (6)	20 Aug 2020 19:55:23

US3752173
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 09:45:09
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:55:23

FDA-CBER-2022-1614-3171441

US3752173
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 09:45:09
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered 'Jan 2015'	System	20 Aug 2020 19:55:23

FDA-CBER-2022-1614-3171442

US3752173
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 09:45:09
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered '2015'	System	20 Aug 2020 19:55:23

FDA-CBER-2022-1614-3171443

US3752173
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 09:45:09
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered 'Jan 2015'	System	20 Aug 2020 19:55:23

FDA-CBER-2022-1614-3171444

US3752173
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 09:45:09
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered '2015'	System	20 Aug 2020 19:55:23

FDA-CBER-2022-1614-3171445

US3752173
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:45:09
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
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: GERD - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 19:57:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 19:57:32
Data point term sent to Coder	System	20 Aug 2020 19:55:59
User entered 'GERD/reflux'	(b) (4), (b) (6)	20 Aug 2020 19:55:45

US3752173
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:45:09
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'un UNK 2002'	(b) (4), (b) (6)	20 Aug 2020 19:55:45

FDA-CBER-2022-1614-3171447

US3752173
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:45:09
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:55:45

FDA-CBER-2022-1614-3171448

US3752173
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:45:09
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 19:55:45

US3752173
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:45:09
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:55:45

US3752173
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:45:09
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:55:45

FDA-CBER-2022-1614-3171451

US3752173
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:45:09
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered 'Jan 2002'	System	20 Aug 2020 19:55:45

FDA-CBER-2022-1614-3171452

US3752173
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:45:09
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered '2002'	System	20 Aug 2020 19:55:45

FDA-CBER-2022-1614-3171453

US3752173
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:45:09
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered empty.	System	20 Aug 2020 19:55:45

FDA-CBER-2022-1614-3171454

US3752173
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:45:09
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered empty.	System	20 Aug 2020 19:55:45

FDA-CBER-2022-1614-3171455

US3752173
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 09:45:09
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gout, unspecified - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 00:33:32
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 00:33:32
User closed query 'Per DM CLR: Please update the condition to include the location of Gout (i.e. bilateral, left, right - big toe, ankles, knees, elbows, wrists, fingers, etc). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 14:15:39
Data point term sent to Coder	System	28 Oct 2020 16:07:16
Query 'Per DM CLR: Please update the condition to include the location of Gout (i.e. bilateral, left, right - big toe, ankles, knees, elbows, wrists, fingers, etc). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 16:06:41
Coding entries removed.	(b) (4), (b) (6)	28 Oct 2020 16:06:34
User entered 'GOUT (location unknown)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 16:06:34
User opened query 'Per DM CLR: Please update the condition to include the location of Gout (i.e. bilateral, left, right - big toe, ankles, knees, elbows, wrists, fingers, etc). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 16:00:26

US3752173
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 09:45:09
Condition

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gout - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 19:58:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 19:58:20
Data point term sent to Coder	System	20 Aug 2020 19:57:00
User entered 'Gout'	(b) (4), (b) (6)	20 Aug 2020 19:56:07

US3752173
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 09:45:09
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'un UNK 2015'	(b) (4), (b) (6)	20 Aug 2020 19:56:07

US3752173
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 09:45:09
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:56:07

US3752173
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 09:45:09
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 19:56:07

US3752173
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 09:45:09
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:56:07

US3752173
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 09:45:09
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:56:07

US3752173
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 09:45:09
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered 'Jan 2015'	System	20 Aug 2020 19:56:07

FDA-CBER-2022-1614-3171463

US3752173
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 09:45:09
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered '2015'	System	20 Aug 2020 19:56:07

FDA-CBER-2022-1614-3171464

US3752173
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 09:45:09
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered empty.	System	20 Aug 2020 19:56:07

US3752173
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 09:45:09
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered empty.	System	20 Aug 2020 19:56:07

FDA-CBER-2022-1614-3171466

US3752173
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 09:45:09
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Low back pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 19:58:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 19:58:20
Data point term sent to Coder	System	20 Aug 2020 19:57:02
User entered 'Low back pain'	(b) (4), (b) (6)	20 Aug 2020 19:56:25

US3752173
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 09:45:09
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'un UNK 2015'	(b) (4), (b) (6)	20 Aug 2020 19:56:25

US3752173
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 09:45:09
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:56:25

US3752173
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 09:45:09
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 19:56:25

US3752173
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 09:45:09
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:56:25

US3752173
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 09:45:09
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:56:25

US3752173
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 09:45:09
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered 'Jan 2015'	System	20 Aug 2020 19:56:25

FDA-CBER-2022-1614-3171473

US3752173
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 09:45:09
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered '2015'	System	20 Aug 2020 19:56:25

FDA-CBER-2022-1614-3171474

US3752173
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 09:45:09
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered empty.	System	20 Aug 2020 19:56:25

FDA-CBER-2022-1614-3171475

US3752173
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 09:45:09
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered empty.	System	20 Aug 2020 19:56:25

FDA-CBER-2022-1614-3171476

US3752173
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 09:45:09
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Skin neoplasms malignant and unspecified, HLT: Skin neoplasms malignant and unspecified (excl melanoma), PT: Basal cell carcinoma, LLT: Basal cell carcinoma face - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 21:32:28
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 21:32:28
Data point term sent to Coder	System	20 Aug 2020 20:00:09
User entered 'Basal cell cancer on face'	(b) (4), (b) (6)	20 Aug 2020 19:59:24

US3752173
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 09:45:09
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'un UNK 2019'	(b) (4), (b) (6)	20 Aug 2020 19:59:24

US3752173
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 09:45:09
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:59:24

FDA-CBER-2022-1614-3171479

US3752173
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 09:45:09
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 19:59:24

US3752173
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 09:45:09
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'un UNK 2019'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:59:24

US3752173
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 09:45:09
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:59:24

US3752173
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 09:45:09
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered 'Jan 2019'	System	20 Aug 2020 19:59:24

FDA-CBER-2022-1614-3171483

US3752173
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 09:45:09
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered '2019'	System	20 Aug 2020 19:59:24

FDA-CBER-2022-1614-3171484

US3752173
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 09:45:09
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered 'Jan 2019'	System	20 Aug 2020 19:59:24

FDA-CBER-2022-1614-3171485

US3752173
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 09:45:09
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered '2019'	System	20 Aug 2020 19:59:24

FDA-CBER-2022-1614-3171486

US3752173
Folder: Screening
Form: Medical History (11)
Generated On: 10 Jun 2021 09:45:09
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic signs, symptoms and disorders NEC, PT: Prostatomegaly, LLT: Enlarged prostate - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 09:59:21
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 09:59:21
Data point term sent to Coder	System	20 Aug 2020 20:00:12
User entered 'Prostate enlargement'	(b) (4), (b) (6)	20 Aug 2020 19:59:45

FDA-CBER-2022-1614-3171487

US3752173
Folder: Screening
Form: Medical History (11)
Generated On: 10 Jun 2021 09:45:09
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'un UNK 2004'	(b) (4), (b) (6)	20 Aug 2020 19:59:45

US3752173
Folder: Screening
Form: Medical History (11)
Generated On: 10 Jun 2021 09:45:09
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:59:45

FDA-CBER-2022-1614-3171489

US3752173
Folder: Screening
Form: Medical History (11)
Generated On: 10 Jun 2021 09:45:09
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 19:59:45

US3752173
Folder: Screening
Form: Medical History (11)
Generated On: 10 Jun 2021 09:45:09
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 19:59:45

US3752173
Folder: Screening
Form: Medical History (11)
Generated On: 10 Jun 2021 09:45:09
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 19:59:45

US3752173
Folder: Screening
Form: Medical History (11)
Generated On: 10 Jun 2021 09:45:09
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered 'Jan 2004'	System	20 Aug 2020 19:59:45

US3752173
Folder: Screening
Form: Medical History (11)
Generated On: 10 Jun 2021 09:45:09
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered '2004'	System	20 Aug 2020 19:59:45

FDA-CBER-2022-1614-3171494

US3752173
Folder: Screening
Form: Medical History (11)
Generated On: 10 Jun 2021 09:45:09
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered empty.	System	20 Aug 2020 19:59:45

US3752173
Folder: Screening
Form: Medical History (11)
Generated On: 10 Jun 2021 09:45:09
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered empty.	System	20 Aug 2020 19:59:45

FDA-CBER-2022-1614-3171496

US3752173
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 09:45:09
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User coded data point as SOC: Surgical and medical procedures, HLGT: Skin and subcutaneous tissue therapeutic procedures, HLT: Skin grafts, PT: Skin graft, LLT: Skin graft - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 02:43:35
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Sep 2020 02:43:35
Data point term sent to Coder	System	20 Aug 2020 20:01:15
User entered 'Island Peticoh Transplant left hand'	(b) (4), (b) (6)	20 Aug 2020 20:00:32

US3752173
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 09:45:09
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:00:32

US3752173
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 09:45:09
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '1'	(b) (4), (b) (6)	20 Aug 2020 20:00:32

FDA-CBER-2022-1614-3171499

US3752173
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 09:45:09
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:00:32

US3752173
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 09:45:09
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:00:32

US3752173
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 09:45:09
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '1'	(b) (4), (b) (6)	20 Aug 2020 20:00:32

US3752173
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 09:45:09
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered empty.	System	20 Aug 2020 20:00:32

US3752173
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 09:45:09
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered empty.	System	20 Aug 2020 20:00:32

US3752173
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 09:45:09
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered empty.	System	20 Aug 2020 20:00:32

US3752173
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 09:45:09
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered empty.	System	20 Aug 2020 20:00:32

US3752173
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 09:45:09
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Limb therapeutic procedures, PT: Limb reconstructive surgery, LLT: Limb reconstructive surgery - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 10:52:56
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 10:52:56
Data point term sent to Coder	System	20 Aug 2020 20:01:15
User entered 'Reconstructive left hand surgery'	(b) (4), (b) (6)	20 Aug 2020 20:00:59

US3752173
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 09:45:09
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'un UNK 1979'	(b) (4), (b) (6)	20 Aug 2020 20:00:59

US3752173
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 09:45:09
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 20:00:59

US3752173
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 09:45:09
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:00:59

US3752173
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 09:45:09
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'un UNK 1979'	(b) (4), (b) (6)	20 Aug 2020 20:00:59

US3752173
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 09:45:09
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 20:00:59

US3752173
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 09:45:09
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered 'Jan 1979'	System	20 Aug 2020 20:00:59

US3752173
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 09:45:09
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered '1979'	System	20 Aug 2020 20:00:59

US3752173
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 09:45:09
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered 'Jan 1979'	System	20 Aug 2020 20:00:59

US3752173
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 09:45:09
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered '1979'	System	20 Aug 2020 20:00:59

US3752173
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 09:45:09
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholecystitis, LLT: Cholecystitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 13:15:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 13:15:39
Data point term sent to Coder	System	13 Oct 2020 13:14:11
User entered 'CHOLECYSTITIS'	(b) (4), (b) (6)	13 Oct 2020 13:13:55

US3752173
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 09:45:09
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'UN UNK 2015'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 13:13:55

US3752173
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 09:45:09
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '0'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 13:13:55

US3752173
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 09:45:09
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 13:13:55

US3752173
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 09:45:09
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'UN UNK 2015'	(b) (4), (b) (6)	13 Oct 2020 13:13:55

US3752173
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 09:45:09
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 13:13:55

US3752173
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 09:45:09
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered 'Jan 2015'	System	13 Oct 2020 13:13:55

US3752173
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 09:45:09
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered '2015'	System	13 Oct 2020 13:13:55

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US3752173
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 09:45:09
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered 'Jan 2015'	System	13 Oct 2020 13:13:55

US3752173
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 09:45:09
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered '2015'	System	13 Oct 2020 13:13:55

FDA-CBER-2022-1614-3171526

US3752173
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 09:45:09
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Nov 2020 17:05:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Nov 2020 17:05:46
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Nov 2020 16:50:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Nov 2020 16:50:46
Data point term sent to Coder	System	18 Nov 2020 16:49:38
User entered 'CORONARY ARTERY DISEASE'	Amanda Horn (b) (4) (b) (4)	18 Nov 2020 16:49:14

US3752173
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 09:45:09
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'UN Dec 2015'	Amanda Horn (b) (4) (b) (4)	18 Nov 2020 16:49:14

US3752173
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 09:45:09
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User entered '0'	Amanda Horn (b) (4) (b) (4)	18 Nov 2020 16:49:14

US3752173
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 09:45:09
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	18 Nov 2020 16:49:14

US3752173
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 09:45:09
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User entered empty.	Amanda Horn (b) (4) (b) (4)	18 Nov 2020 16:49:14

US3752173
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 09:45:09
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User entered '0'	Amanda Horn (b) (4) (b) (4)	18 Nov 2020 16:49:14

US3752173
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 09:45:09
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered 'Dec 2015'	System	18 Nov 2020 16:49:14

US3752173
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 09:45:09
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered '2015'	System	18 Nov 2020 16:49:14

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US3752173
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 09:45:09
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered empty.	System	18 Nov 2020 16:49:14

US3752173
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 09:45:09
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered empty.	System	18 Nov 2020 16:49:14

FDA-CBER-2022-1614-3171536

US3752173
Folder: Screening
Form: Medical History (16)
Generated On: 10 Jun 2021 09:45:09
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User coded data point as SOC: Cardiac disorders, HLGT: Myocardial disorders, HLT: Cardiomyopathies, PT: Cardiomyopathy, LLT: Cardiomyopathy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Nov 2020 16:51:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Nov 2020 16:51:45
Data point term sent to Coder	System	18 Nov 2020 16:50:40
User entered 'CARDIOMYOPATHY'	Amanda Horn (b) (4) (b) (4)	18 Nov 2020 16:50:31

US3752173
Folder: Screening
Form: Medical History (16)
Generated On: 10 Jun 2021 09:45:09
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'UN UNK 2015'	Amanda Horn (b) (4) (b) (4)	18 Nov 2020 16:50:31

US3752173
Folder: Screening
Form: Medical History (16)
Generated On: 10 Jun 2021 09:45:09
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User entered '0'	Amanda Horn (b) (4) (b) (4)	18 Nov 2020 16:50:31

US3752173
Folder: Screening
Form: Medical History (16)
Generated On: 10 Jun 2021 09:45:09
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	18 Nov 2020 16:50:31

US3752173
Folder: Screening
Form: Medical History (16)
Generated On: 10 Jun 2021 09:45:09
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User entered empty.	Amanda Horn (b) (4) (b) (4)	18 Nov 2020 16:50:31

US3752173
Folder: Screening
Form: Medical History (16)
Generated On: 10 Jun 2021 09:45:09
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User entered '0'	Amanda Horn (b) (4) (b) (4)	18 Nov 2020 16:50:31

US3752173
Folder: Screening
Form: Medical History (16)
Generated On: 10 Jun 2021 09:45:09
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered 'Jan 2015'	System	18 Nov 2020 16:50:31

US3752173
Folder: Screening
Form: Medical History (16)
Generated On: 10 Jun 2021 09:45:09
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered '2015'	System	18 Nov 2020 16:50:31

FDA-CBER-2022-1614-3171544

US3752173
Folder: Screening
Form: Medical History (16)
Generated On: 10 Jun 2021 09:45:09
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered empty.	System	18 Nov 2020 16:50:31

FDA-CBER-2022-1614-3171545

US3752173
Folder: Screening
Form: Medical History (16)
Generated On: 10 Jun 2021 09:45:09
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered empty.	System	18 Nov 2020 16:50:31

FDA-CBER-2022-1614-3171546

US3752173
Folder: Screening
Form: Medical History (17)
Generated On: 10 Jun 2021 09:45:09
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
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 Nov 2020 16:52:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Nov 2020 16:52:47
Data point term sent to Coder	System	18 Nov 2020 16:51:40
User entered 'HYPERTENSION'	Amanda Horn (b) (4) (b) (4)	18 Nov 2020 16:51:08

US3752173
Folder: Screening
Form: Medical History (17)
Generated On: 10 Jun 2021 09:45:09
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	18 Nov 2020 16:51:21
User opened query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	18 Nov 2020 16:51:08
User entered empty.	Amanda Horn (b) (4) (b) (4)	18 Nov 2020 16:51:08

US3752173
Folder: Screening
Form: Medical History (17)
Generated On: 10 Jun 2021 09:45:09
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User entered '1' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	18 Nov 2020 16:51:21
User entered '0'	Amanda Horn (b) (4) (b) (4)	18 Nov 2020 16:51:08

US3752173
Folder: Screening
Form: Medical History (17)
Generated On: 10 Jun 2021 09:45:09
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	18 Nov 2020 16:51:08

US3752173
Folder: Screening
Form: Medical History (17)
Generated On: 10 Jun 2021 09:45:09
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User entered empty.	Amanda Horn (b) (4) (b) (4)	18 Nov 2020 16:51:08

US3752173
Folder: Screening
Form: Medical History (17)
Generated On: 10 Jun 2021 09:45:09
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User entered '0'	Amanda Horn (b) (4) (b) (4)	18 Nov 2020 16:51:08

US3752173
Folder: Screening
Form: Medical History (17)
Generated On: 10 Jun 2021 09:45:09
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered empty.	System	18 Nov 2020 16:51:08

US3752173
Folder: Screening
Form: Medical History (17)
Generated On: 10 Jun 2021 09:45:09
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered empty.	System	18 Nov 2020 16:51:08

FDA-CBER-2022-1614-3171554

US3752173
Folder: Screening
Form: Medical History (17)
Generated On: 10 Jun 2021 09:45:09
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered empty.	System	18 Nov 2020 16:51:08

FDA-CBER-2022-1614-3171555

US3752173
Folder: Screening
Form: Medical History (17)
Generated On: 10 Jun 2021 09:45:09
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered empty.	System	18 Nov 2020 16:51:08

FDA-CBER-2022-1614-3171556

US3752173
Folder: Screening
Form: Medical History (18)
Generated On: 10 Jun 2021 09:45:09
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User coded data point as SOC: Investigations, HLGT: Cardiac and vascular investigations (excl enzyme tests), HLT: Cardiac imaging procedures, PT: Catheterisation cardiac, LLT: Cardiac catheterization - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Nov 2020 16:54:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Nov 2020 16:54:45
Data point term sent to Coder	System	18 Nov 2020 16:53:45
User entered 'CARDIAC CATHETERIZATION'	Amanda Horn (b) (4) (b) (4)	18 Nov 2020 16:53:02

US3752173
Folder: Screening
Form: Medical History (18)
Generated On: 10 Jun 2021 09:45:09
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User entered '6 Nov 2015'	Amanda Horn (b) (4) (b) (4)	18 Nov 2020 16:53:02

US3752173
Folder: Screening
Form: Medical History (18)
Generated On: 10 Jun 2021 09:45:09
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User entered '0'	Amanda Horn (b) (4) (b) (4)	18 Nov 2020 16:53:02

US3752173
Folder: Screening
Form: Medical History (18)
Generated On: 10 Jun 2021 09:45:09
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	18 Nov 2020 16:53:02

US3752173
Folder: Screening
Form: Medical History (18)
Generated On: 10 Jun 2021 09:45:09
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User entered '06 Nov 2015'	Amanda Horn (b) (4) (b) (4)	18 Nov 2020 16:53:02

US3752173
Folder: Screening
Form: Medical History (18)
Generated On: 10 Jun 2021 09:45:09
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User entered '0'	Amanda Horn (b) (4) (b) (4)	18 Nov 2020 16:53:02

US3752173
Folder: Screening
Form: Medical History (18)
Generated On: 10 Jun 2021 09:45:09
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered 'Nov 2015'	System	18 Nov 2020 16:53:02

FDA-CBER-2022-1614-3171563

US3752173
Folder: Screening
Form: Medical History (18)
Generated On: 10 Jun 2021 09:45:09
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered '2015'	System	18 Nov 2020 16:53:02

FDA-CBER-2022-1614-3171564

US3752173
Folder: Screening
Form: Medical History (18)
Generated On: 10 Jun 2021 09:45:09
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered 'Nov 2015'	System	18 Nov 2020 16:53:02

FDA-CBER-2022-1614-3171565

US3752173
Folder: Screening
Form: Medical History (18)
Generated On: 10 Jun 2021 09:45:09
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered '2015'	System	18 Nov 2020 16:53:02

FDA-CBER-2022-1614-3171566

US3752173
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:45:09
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 20:02:11

US3752173
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:45:09
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '20 Aug 2020'	(b) (4), (b) (6)	20 Aug 2020 20:02:11

US3752173
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:45:09
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '10:15'	(b) (4), (b) (6)	20 Aug 2020 20:02:11

US3752173
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:45:09
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered '20 Aug 2020 10:15'	System	20 Aug 2020 20:02:11

US3752173
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:45:09
Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '70.0' in	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:02:11
DataPoint set to visible.	System	20 Aug 2020 15:57:18

US3752173
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:45:09
Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '195.1' lb	(b) (4), (b) (6)	20 Aug 2020 20:02:11
DataPoint set to visible.	System	20 Aug 2020 15:57:18

US3752173
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:45:09
BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Amendment Manager: User entered '28.05247'	System	17 Sep 2020 00:15:57
User entered '28.1'	System	20 Aug 2020 20:02:11
DataPoint set to visible.	System	20 Aug 2020 15:57:18

FDA-CBER-2022-1614-3171573

US3752173
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:45:09
BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered 'kg/m2'	System	20 Aug 2020 20:02:11
DataPoint set to visible.	System	20 Aug 2020 15:57:18

US3752173
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:45:09
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 15:25:05
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 14:23:33
User entered '097.9' F	(b) (4), (b) (6)	20 Aug 2020 20:02:11

US3752173
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:45:09
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:51:16
User entered 'Oral (Oral)'	(b) (4), (b) (6)	20 Aug 2020 20:02:11

US3752173
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:45:09
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:02:11

US3752173
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:45:09
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 14:23:33
User entered '061'	(b) (4), (b) (6)	20 Aug 2020 20:02:11

FDA-CBER-2022-1614-3171578

US3752173
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:45:09
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered 'bpm'	System	20 Aug 2020 20:02:11

FDA-CBER-2022-1614-3171579

US3752173
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:45:09
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 14:23:33
User entered '16'	(b) (4), (b) (6)	20 Aug 2020 20:02:11

US3752173
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:45:09
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered 'breaths/min'	System	20 Aug 2020 20:02:11

FDA-CBER-2022-1614-3171581

US3752173
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:45:09
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 14:23:33
User entered '116'	(b) (4), (b) (6)	20 Aug 2020 20:02:11

US3752173
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:45:09
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered 'mmHg'	System	20 Aug 2020 20:02:11

FDA-CBER-2022-1614-3171583

US3752173
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:45:09
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 14:23:33
User entered '074'	(b) (4), (b) (6)	20 Aug 2020 20:02:11

US3752173
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:45:09
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered 'mmHg'	System	20 Aug 2020 20:02:11

FDA-CBER-2022-1614-3171585

US3752173
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:45:09
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12

FDA-CBER-2022-1614-3171586

US3752173
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:45:09
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12

FDA-CBER-2022-1614-3171587

US3752173
Folder: Screening
Form: Physical Examination
Generated On: 10 Jun 2021 09:45:09
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 19:29:56
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 18:51:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 20:02:21

US3752173
Folder: Screening
Form: Physical Examination
Generated On: 10 Jun 2021 09:45:09
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '20 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 19:29:56
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 18:51:30
User entered '20 Aug 2020'	(b) (4), (b) (6)	20 Aug 2020 20:02:21

US3752173
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:45:09
Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:06:26

US3752173
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:45:09
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:06:26

US3752173
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:45:09
Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:06:26

US3752173
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:45:09
Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:06:26

US3752173
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:45:09
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:06:26

US3752173
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:45:09
Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:06:26

US3752173
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:45:09
Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:06:26

US3752173
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:45:09
Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:06:26

US3752173
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:45:09
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:06:26

US3752173
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:45:09
Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:06:26

US3752173
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:45:09
Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:06:26

US3752173
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:45:09
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:06:26

US3752173
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:45:09
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:06:26

US3752173
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:45:09
No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '1'	(b) (4), (b) (6)	20 Aug 2020 20:06:26

US3752173
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:45:09
Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 20:06:26

US3752173
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:45:09
Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:06:26

US3752173
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:45:09
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 20:06:26

US3752173
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:45:09
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:06:26

US3752173
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:45:09
Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 20:06:26

US3752173
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:45:09
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 20:06:26

US3752173
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:45:09
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:06:26

US3752173
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 09:45:09
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:09:08
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:08:12

FDA-CBER-2022-1614-3171611

US3752173
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 09:45:09
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:09:08
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '20 Aug 2020'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:08:12

FDA-CBER-2022-1614-3171612

US3752173
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 09:45:09
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:09:08
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:08:12

US3752173
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 09:45:09
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:09:08
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User entered 'VISIT1'	System	20 Aug 2020 20:08:12

US3752173
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:45:09
What was the date of randomization? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:09:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User entered '20 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 15:40:23

FDA-CBER-2022-1614-3171615

US3752173
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:45:09
What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:09:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 05:51:22
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:51:22
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	20 Aug 2020 15:40:23
User entered '187144' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 15:40:23

US3752173
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:45:09
In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:09:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 15:40:23

US3752173
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:45:09
Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:09:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:08:26

US3752173
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:45:09
Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:09:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:08:26

US3752173
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:45:09
Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:09:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:08:26

FDA-CBER-2022-1614-3171620

US3752173
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:45:09
Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:09:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:08:26

FDA-CBER-2022-1614-3171621

US3752173
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:45:09
Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:09:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:08:26

FDA-CBER-2022-1614-3171622

US3752173
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:45:09
Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:09:15
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 15:25:14
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:36:52
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:43:52

US3752173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:45:09
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:05
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User closed query 'Per CDM: units of measure (HT cm/in or WT kg/lbs.) should not be recorded if value is blank or ND. Please update the HT and/or WT by of measure by selecting … in the drop down box provided. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Sep 2020 15:53:27
Query 'Per CDM: units of measure (HT cm/in or WT kg/lbs.) should not be recorded if value is blank or ND. Please update the HT and/or WT by of measure by selecting … in the drop down box provided. Thank you. ' answered with 'done' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 13:37:02
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 13:36:56
User opened query 'Per CDM: units of measure (HT cm/in or WT kg/lbs.) should not be recorded if value is blank or ND. Please update the HT and/or WT by of measure by selecting … in the drop down box provided. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 12:46:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 14:23:52
User entered '70.0' in	(b) (4), (b) (6)	20 Aug 2020 20:09:42

US3752173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:45:09
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:05
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Sep 2020 13:36:56
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 14:23:52
User entered '195.1' lb	(b) (4), (b) (6)	20 Aug 2020 20:09:42

US3752173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:45:09
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:05
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User closed query 'Per CDM: units of measure (HT cm/in or WT kg/lbs.) should not be recorded if value is blank or ND. Please update the HT and/or WT by of measure by selecting … in the drop down box provided. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Sep 2020 15:53:27
Query 'Per CDM: units of measure (HT cm/in or WT kg/lbs.) should not be recorded if value is blank or ND. Please update the HT and/or WT by of measure by selecting … in the drop down box provided. Thank you. ' answered with 'done' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 13:37:02
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 13:36:56
User opened query 'Per CDM: units of measure (HT cm/in or WT kg/lbs.) should not be recorded if value is blank or ND. Please update the HT and/or WT by of measure by selecting … in the drop down box provided. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 12:46:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 14:23:52
User entered '70.0' in	(b) (4), (b) (6)	20 Aug 2020 20:09:42

US3752173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:45:09
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:05
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 13:36:56
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 14:23:52
User entered '195.1' lb	(b) (4), (b) (6)	20 Aug 2020 20:09:42

US3752173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:45:09
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:05
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	20 Aug 2020 20:09:42

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US3752173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:45:09
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:05
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:09:42

FDA-CBER-2022-1614-3171629

US3752173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:45:09
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:05
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '20 Aug 2020'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:09:42

US3752173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:45:09
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:05
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '10:15'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:09:42

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US3752173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:45:09
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:05
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User entered '20 Aug 2020 10:15'	System	20 Aug 2020 20:09:42

US3752173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:45:09
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:05
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '97.9' F reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	21 Sep 2020 15:25:32
User entered '097.9' F	(b) (4), (b) (6)	20 Aug 2020 20:09:42

US3752173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:45:09
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:05
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	20 Aug 2020 20:10:16
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 20:10:16
User opened query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 20:09:42
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:09:42

US3752173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:45:09
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:05
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:09:42

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US3752173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:45:09
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:05
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	20 Aug 2020 20:10:16
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	20 Aug 2020 20:10:16
User entered '061' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 20:10:16
User opened query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 20:09:42
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:09:42

US3752173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:45:09
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:05
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User entered 'bpm'	System	20 Aug 2020 20:10:16
User entered empty.	System	20 Aug 2020 20:09:42

US3752173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:45:09
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:05
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	20 Aug 2020 20:10:16
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	20 Aug 2020 20:10:16
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 20:10:16
User opened query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 20:09:42
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:09:42

US3752173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:45:09
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:05
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User entered 'breaths/min'	System	20 Aug 2020 20:10:16
User entered empty.	System	20 Aug 2020 20:09:42

FDA-CBER-2022-1614-3171639

US3752173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:45:09
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:05
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	20 Aug 2020 20:10:16
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	20 Aug 2020 20:10:16
User entered '116' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 20:10:16
User opened query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 20:09:42
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:09:42

US3752173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:45:09
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:05
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User entered 'mmHg'	System	20 Aug 2020 20:10:16
User entered empty.	System	20 Aug 2020 20:09:42

FDA-CBER-2022-1614-3171641

US3752173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:45:09
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:05
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	20 Aug 2020 20:10:16
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	20 Aug 2020 20:10:16
User entered '074' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 20:10:16
User opened query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 20:09:42
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:09:42

US3752173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:45:09
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:05
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User entered 'mmHg'	System	20 Aug 2020 20:10:16
User entered empty.	System	20 Aug 2020 20:09:42

US3752173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:45:09
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:05
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User closed query 'Per CDM: units of measure (HT cm/in or WT kg/lbs.) should not be recorded if value is blank or ND. Please update the HT and/or WT by of measure by selecting … in the drop down box provided. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Sep 2020 15:53:27
Query 'Per CDM: units of measure (HT cm/in or WT kg/lbs.) should not be recorded if value is blank or ND. Please update the HT and/or WT by of measure by selecting … in the drop down box provided. Thank you. ' answered with 'done' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 13:37:02
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 13:36:56
User opened query 'Per CDM: units of measure (HT cm/in or WT kg/lbs.) should not be recorded if value is blank or ND. Please update the HT and/or WT by of measure by selecting … in the drop down box provided. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 12:46:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 14:23:52
User entered '70.0' in	(b) (4), (b) (6)	20 Aug 2020 20:09:42

US3752173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:45:09
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:05
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Sep 2020 13:36:56
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 14:23:52
User entered '195.1' lb	(b) (4), (b) (6)	20 Aug 2020 20:09:42

US3752173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:45:09
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:05
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	20 Aug 2020 20:09:42

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US3752173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:45:09
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:05
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:09:42

FDA-CBER-2022-1614-3171647

US3752173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:45:09
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:05
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '20 Aug 2020'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:09:42

US3752173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:45:09
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:05
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4) System	21 Aug 2020 05:51:19
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	System	20 Aug 2020 20:09:42
User entered '11:20'	(b) (4), (b) (6)	20 Aug 2020 20:09:42

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US3752173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:45:09
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:05
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User entered '20 Aug 2020 11:20'	System	20 Aug 2020 20:09:42

US3752173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:45:09
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:05
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '98.7' F	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:09:42

FDA-CBER-2022-1614-3171651

US3752173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:45:09
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:05
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	20 Aug 2020 20:10:46
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 20:10:46
User opened query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 20:09:42
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:09:42

US3752173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:45:09
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:05
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:09:42

US3752173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:45:09
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:05
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	20 Aug 2020 20:10:46
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	20 Aug 2020 20:10:46
User entered '60' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 20:10:46
User opened query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 20:09:42
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:09:42

US3752173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:45:09
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:05
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User entered 'bpm'	System	20 Aug 2020 20:10:46
User entered empty.	System	20 Aug 2020 20:09:42

US3752173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:45:09
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:05
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	20 Aug 2020 20:10:46
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	20 Aug 2020 20:10:46
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 20:10:46
User opened query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 20:09:42
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:09:42

US3752173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:45:09
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:05
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User entered 'breaths/min'	System	20 Aug 2020 20:10:46
User entered empty.	System	20 Aug 2020 20:09:42

US3752173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:45:09
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:05
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	20 Aug 2020 20:10:46
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	20 Aug 2020 20:10:46
User entered '110' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 20:10:46
User opened query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 20:09:42
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:09:42

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US3752173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:45:09
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:05
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User entered 'mmHg'	System	20 Aug 2020 20:10:46
User entered empty.	System	20 Aug 2020 20:09:42

US3752173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:45:09
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:05
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	20 Aug 2020 20:10:46
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	20 Aug 2020 20:10:46
User entered '70' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Aug 2020 20:10:46
User opened query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 20:09:42
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:09:42

US3752173
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:45:09
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:05
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User entered 'mmHg'	System	20 Aug 2020 20:10:46
User entered empty.	System	20 Aug 2020 20:09:42

FDA-CBER-2022-1614-3171661

US3752173
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 10 Jun 2021 09:45:09
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:12
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User closed query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day then completion of the PE form is only required to be completed using the PE form located in the screening folder. Completion of the PE form within the Visit 1 Day 1 folder should be left blank except for the response to “Was the physical examination performed?” This should be “No”. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Sep 2020 16:26:06
Query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day then completion of the PE form is only required to be completed using the PE form located in the screening folder. Completion of the PE form within the Visit 1 Day 1 folder should be left blank except for the response to “Was the physical examination performed?” This should be “No”. Please update accordingly.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 13:54:37
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 13:54:31
User opened query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day then completion of the PE form is only required to be completed using the PE form located in the screening folder. Completion of the PE form within the Visit 1 Day 1 folder should be left blank except for the response to “Was the physical examination performed?” This should be “No”. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 20:49:54

US3752173
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 10 Jun 2021 09:45:09
Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 20:10:57

US3752173
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 10 Jun 2021 09:45:09
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:12
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	03 Sep 2020 13:54:31
User entered '20 Aug 2020'	(b) (4), (b) (6)	20 Aug 2020 20:10:57

US3752173
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:45:09
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:18
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 15:57:50

US3752173
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:45:09
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:18
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 15:57:50

US3752173
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:45:09
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:18
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 15:57:50

US3752173
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:45:09
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:18
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User entered 'MRNA-1273 OR PLACEBO'	System	20 Aug 2020 15:57:50

US3752173
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:45:09
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:18
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '20 Aug 2020'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 15:57:50

US3752173
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:45:09
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:18
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '10:46'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 15:57:50

FDA-CBER-2022-1614-3171670

US3752173
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:45:09
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:18
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User entered '20 Aug 2020 10:46'	System	20 Aug 2020 15:57:50

FDA-CBER-2022-1614-3171671

US3752173
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:45:09
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:18
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 15:57:50

US3752173
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:45:09
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:18
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User entered 'ONCE'	System	20 Aug 2020 15:57:50

US3752173
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:45:09
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:18
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User entered 'INTRAMUSCULAR'	System	20 Aug 2020 15:57:50

US3752173
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:45:09
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:24
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:11:28

US3752173
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:45:09
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:24
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '20 Aug 2020'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:11:28

FDA-CBER-2022-1614-3171676

US3752173
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:45:09
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:24
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '10:29'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:11:28

FDA-CBER-2022-1614-3171677

US3752173
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:45:09
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:24
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User entered '20 Aug 2020 10:29'	System	20 Aug 2020 20:11:28

FDA-CBER-2022-1614-3171678

US3752173
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 10 Jun 2021 09:45:09
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:30
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '20 Aug 2020'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:11:46

FDA-CBER-2022-1614-3171679

US3752173
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:45:09
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:30
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	20 Aug 2020 20:11:46

US3752173
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:45:09
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:30
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:11:46

FDA-CBER-2022-1614-3171681

US3752173
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:45:09
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:30
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '10:27'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:11:46

US3752173
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:45:09
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:30
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User entered '20 Aug 2020 10:27'	System	20 Aug 2020 20:11:46

FDA-CBER-2022-1614-3171683

US3752173
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:45:09
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:30
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	20 Aug 2020 20:11:46

US3752173
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:45:09
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:30
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:11:46

US3752173
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:45:09
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:30
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:11:46

US3752173
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:45:09
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:30
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User entered empty.	System	20 Aug 2020 20:11:46

US3752173
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 10 Jun 2021 09:45:09
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:37
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 20:12:02

FDA-CBER-2022-1614-3171688

US3752173
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 10 Jun 2021 09:45:09
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:37
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User entered '1'	System	20 Aug 2020 20:12:02

US3752173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:45:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
Data entry locked.	System	20 Aug 2020 15:57:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 15:57:50

US3752173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:45:09
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T11:23:48', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '15e19f1b-ab03-4a0a-8697-7be8dd8b495d'	System	20 Aug 2020 16:25:25
User entered 'Yes (Y)'	System	20 Aug 2020 16:25:25

FDA-CBER-2022-1614-3171691

US3752173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:45:09
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T11:24:09', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '15e19f1b-ab03-4a0a-8697-7be8dd8b495d'	System	20 Aug 2020 16:25:25
User entered '98.7'	System	20 Aug 2020 16:25:25

FDA-CBER-2022-1614-3171692

US3752173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:45:09
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T11:24:18', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '15e19f1b-ab03-4a0a-8697-7be8dd8b495d'	System	20 Aug 2020 16:25:25
User entered 'No (N)'	System	20 Aug 2020 16:25:25

US3752173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:45:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T11:24:34', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '15e19f1b-ab03-4a0a-8697-7be8dd8b495d'	System	20 Aug 2020 16:25:25
User entered '20 Aug 2020 11:24'	System	20 Aug 2020 16:25:25

FDA-CBER-2022-1614-3171694

US3752173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:45:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '20 Aug 2020 11:06'	System	20 Aug 2020 15:57:50

FDA-CBER-2022-1614-3171695

US3752173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:45:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '20 Aug 2020 13:36'	System	20 Aug 2020 15:57:50

FDA-CBER-2022-1614-3171696

US3752173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:45:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
Data entry locked.	System	20 Aug 2020 15:57:50
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 15:57:50

US3752173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:45:09
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T18:22:57', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '6e606b31-2f38-4697-b9f2-c0e51e517915'	System	20 Aug 2020 23:23:42
User entered 'Yes (Y)'	System	20 Aug 2020 23:23:42

FDA-CBER-2022-1614-3171698

US3752173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:45:09
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T18:23:15', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '6e606b31-2f38-4697-b9f2-c0e51e517915'	System	20 Aug 2020 23:23:42
User entered '98.2'	System	20 Aug 2020 23:23:42

FDA-CBER-2022-1614-3171699

US3752173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:45:09
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T18:23:22', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '6e606b31-2f38-4697-b9f2-c0e51e517915'	System	20 Aug 2020 23:23:42
User entered 'No (N)'	System	20 Aug 2020 23:23:42

FDA-CBER-2022-1614-3171700

US3752173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:45:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T18:23:33', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '6e606b31-2f38-4697-b9f2-c0e51e517915'	System	20 Aug 2020 23:23:42
User entered '20 Aug 2020 18:23'	System	20 Aug 2020 23:23:42

FDA-CBER-2022-1614-3171701

US3752173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:45:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '20 Aug 2020 14:31'	System	20 Aug 2020 15:57:50

FDA-CBER-2022-1614-3171702

US3752173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:45:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 15:57:50

FDA-CBER-2022-1614-3171703

US3752173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:45:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
Data entry locked.	System	20 Aug 2020 15:57:50
User entered 'Day 2'	System	20 Aug 2020 15:57:50

US3752173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:45:09
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-21T20:37:54', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '5e285eba-cefc-418e-9e7d-e1d0ec0846b3'	System	22 Aug 2020 01:38:25
User entered 'Yes (Y)'	System	22 Aug 2020 01:38:25

FDA-CBER-2022-1614-3171705

US3752173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:45:09
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-21T20:38:06', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '5e285eba-cefc-418e-9e7d-e1d0ec0846b3'	System	22 Aug 2020 01:38:25
User entered '94.2'	System	22 Aug 2020 01:38:25

FDA-CBER-2022-1614-3171706

US3752173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:45:09
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-21T20:38:12', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '5e285eba-cefc-418e-9e7d-e1d0ec0846b3'	System	22 Aug 2020 01:38:25
User entered 'No (N)'	System	22 Aug 2020 01:38:25

US3752173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:45:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-21T20:38:20', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '5e285eba-cefc-418e-9e7d-e1d0ec0846b3'	System	22 Aug 2020 01:38:25
User entered '21 Aug 2020 20:38'	System	22 Aug 2020 01:38:25

FDA-CBER-2022-1614-3171708

US3752173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:45:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 15:57:50

FDA-CBER-2022-1614-3171709

US3752173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:45:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 15:57:50

FDA-CBER-2022-1614-3171710

US3752173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:45:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
Data entry locked.	System	20 Aug 2020 15:57:50
User entered 'Day 3'	System	20 Aug 2020 15:57:50

FDA-CBER-2022-1614-3171711

US3752173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:45:09
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-22T19:35:16', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '30c5eb55-c1d2-42a1-bb23-b51af08fac9c'	System	23 Aug 2020 00:35:49
User entered 'Yes (Y)'	System	23 Aug 2020 00:35:49

FDA-CBER-2022-1614-3171712

US3752173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:45:09
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-22T19:35:28', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '30c5eb55-c1d2-42a1-bb23-b51af08fac9c'	System	23 Aug 2020 00:35:49
User entered '98.0'	System	23 Aug 2020 00:35:49

US3752173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:45:09
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-22T19:35:39', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '30c5eb55-c1d2-42a1-bb23-b51af08fac9c'	System	23 Aug 2020 00:35:49
User entered 'No (N)'	System	23 Aug 2020 00:35:49

FDA-CBER-2022-1614-3171714

US3752173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:45:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-22T19:35:47', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '30c5eb55-c1d2-42a1-bb23-b51af08fac9c'	System	23 Aug 2020 00:35:49
User entered '22 Aug 2020 19:35'	System	23 Aug 2020 00:35:49

FDA-CBER-2022-1614-3171715

US3752173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:45:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 15:57:50

FDA-CBER-2022-1614-3171716

US3752173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:45:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 15:57:50

FDA-CBER-2022-1614-3171717

US3752173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:45:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
Data entry locked.	System	20 Aug 2020 15:57:50
User entered 'Day 4'	System	20 Aug 2020 15:57:50

FDA-CBER-2022-1614-3171718

US3752173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:45:09
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-23T21:23:17', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '6cf1cec4-73a6-4822-ac39-fab0fdfeada2'	System	24 Aug 2020 02:24:39
User entered 'Yes (Y)'	System	24 Aug 2020 02:24:39

FDA-CBER-2022-1614-3171719

US3752173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:45:09
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-23T21:23:26', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '6cf1cec4-73a6-4822-ac39-fab0fdfeada2'	System	24 Aug 2020 02:24:39
User entered '97.2'	System	24 Aug 2020 02:24:39

FDA-CBER-2022-1614-3171720

US3752173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:45:09
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-23T21:23:34', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '6cf1cec4-73a6-4822-ac39-fab0fdfeada2'	System	24 Aug 2020 02:24:39
User entered 'No (N)'	System	24 Aug 2020 02:24:39

FDA-CBER-2022-1614-3171721

US3752173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:45:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-23T21:23:44', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '6cf1cec4-73a6-4822-ac39-fab0fdfeada2'	System	24 Aug 2020 02:24:39
User entered '23 Aug 2020 21:23'	System	24 Aug 2020 02:24:39

FDA-CBER-2022-1614-3171722

US3752173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:45:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 15:57:50

FDA-CBER-2022-1614-3171723

US3752173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:45:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 15:57:50

FDA-CBER-2022-1614-3171724

US3752173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:45:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
Data entry locked.	System	20 Aug 2020 15:57:50
User entered 'Day 5'	System	20 Aug 2020 15:57:50

FDA-CBER-2022-1614-3171725

US3752173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:45:09
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-24T20:34:33', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '9b760e65-da51-47ff-9103-2bbcc7e154d9'	System	25 Aug 2020 01:35:13
User entered 'Yes (Y)'	System	25 Aug 2020 01:35:13

FDA-CBER-2022-1614-3171726

US3752173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:45:09
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-24T20:34:50', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '9b760e65-da51-47ff-9103-2bbcc7e154d9'	System	25 Aug 2020 01:35:13
User entered '97.4'	System	25 Aug 2020 01:35:13

FDA-CBER-2022-1614-3171727

US3752173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:45:09
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-24T20:34:57', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '9b760e65-da51-47ff-9103-2bbcc7e154d9'	System	25 Aug 2020 01:35:13
User entered 'No (N)'	System	25 Aug 2020 01:35:13

US3752173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:45:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-24T20:35:11', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '9b760e65-da51-47ff-9103-2bbcc7e154d9'	System	25 Aug 2020 01:35:13
User entered '24 Aug 2020 20:35'	System	25 Aug 2020 01:35:13

FDA-CBER-2022-1614-3171729

US3752173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:45:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 15:57:50

FDA-CBER-2022-1614-3171730

US3752173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:45:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 15:57:50

FDA-CBER-2022-1614-3171731

US3752173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:45:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
Data entry locked.	System	20 Aug 2020 15:57:50
User entered 'Day 6'	System	20 Aug 2020 15:57:50

US3752173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:45:09
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-25T20:06:21', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'e9304c97-2801-454c-b4b9-7d4ba5c8e06d'	System	26 Aug 2020 01:06:49
User entered 'Yes (Y)'	System	26 Aug 2020 01:06:49

FDA-CBER-2022-1614-3171733

US3752173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:45:09
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-25T20:06:33', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'e9304c97-2801-454c-b4b9-7d4ba5c8e06d'	System	26 Aug 2020 01:06:49
User entered '97.6'	System	26 Aug 2020 01:06:49

FDA-CBER-2022-1614-3171734

US3752173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:45:09
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-25T20:06:38', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'e9304c97-2801-454c-b4b9-7d4ba5c8e06d'	System	26 Aug 2020 01:06:49
User entered 'No (N)'	System	26 Aug 2020 01:06:49

FDA-CBER-2022-1614-3171735

US3752173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:45:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-25T20:06:44', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'e9304c97-2801-454c-b4b9-7d4ba5c8e06d'	System	26 Aug 2020 01:06:49
User entered '25 Aug 2020 20:06'	System	26 Aug 2020 01:06:49

FDA-CBER-2022-1614-3171736

US3752173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:45:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 15:57:50

FDA-CBER-2022-1614-3171737

US3752173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:45:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 15:57:50

FDA-CBER-2022-1614-3171738

US3752173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:45:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
Data entry locked.	System	20 Aug 2020 15:57:50
User entered 'Day 7'	System	20 Aug 2020 15:57:50

FDA-CBER-2022-1614-3171739

US3752173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:45:09
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-26T19:19:06', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'c6645bd2-9bb1-40b4-be66-5527ca2f4839'	System	27 Aug 2020 00:19:43
User entered 'Yes (Y)'	System	27 Aug 2020 00:19:43

FDA-CBER-2022-1614-3171740

US3752173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:45:09
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-26T19:19:18', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'c6645bd2-9bb1-40b4-be66-5527ca2f4839'	System	27 Aug 2020 00:19:43
User entered '97.7'	System	27 Aug 2020 00:19:43

FDA-CBER-2022-1614-3171741

US3752173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:45:09
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-26T19:19:25', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'c6645bd2-9bb1-40b4-be66-5527ca2f4839'	System	27 Aug 2020 00:19:43
User entered 'No (N)'	System	27 Aug 2020 00:19:43

FDA-CBER-2022-1614-3171742

US3752173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:45:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-26T19:19:39', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'c6645bd2-9bb1-40b4-be66-5527ca2f4839'	System	27 Aug 2020 00:19:43
User entered '26 Aug 2020 19:19'	System	27 Aug 2020 00:19:43

FDA-CBER-2022-1614-3171743

US3752173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:45:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 15:57:50

FDA-CBER-2022-1614-3171744

US3752173
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:45:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 15:57:50

FDA-CBER-2022-1614-3171745

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:45:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
Data entry locked.	System	20 Aug 2020 15:57:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 15:57:50

FDA-CBER-2022-1614-3171746

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:45:09
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T11:24:49', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'd9e42f6c-36f7-40f5-a07a-eeedd3b74493'	System	20 Aug 2020 16:26:47
User entered 'None (1)'	System	20 Aug 2020 16:26:47

FDA-CBER-2022-1614-3171747

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:45:09
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T11:24:56', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'd9e42f6c-36f7-40f5-a07a-eeedd3b74493'	System	20 Aug 2020 16:26:47
User entered 'No (N)'	System	20 Aug 2020 16:26:47

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:45:09
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T11:25:01', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'd9e42f6c-36f7-40f5-a07a-eeedd3b74493'	System	20 Aug 2020 16:26:47
User entered 'No (N)'	System	20 Aug 2020 16:26:47

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:45:09
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T11:25:06', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'd9e42f6c-36f7-40f5-a07a-eeedd3b74493'	System	20 Aug 2020 16:26:47
User entered 'None (1)'	System	20 Aug 2020 16:26:47

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:45:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T11:25:12', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'd9e42f6c-36f7-40f5-a07a-eeedd3b74493'	System	20 Aug 2020 16:26:47
User entered '20 Aug 2020 11:25'	System	20 Aug 2020 16:26:47

FDA-CBER-2022-1614-3171751

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:45:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '20 Aug 2020 11:06'	System	20 Aug 2020 15:57:50

FDA-CBER-2022-1614-3171752

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:45:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '20 Aug 2020 13:36'	System	20 Aug 2020 15:57:50

FDA-CBER-2022-1614-3171753

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:45:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
Data entry locked.	System	20 Aug 2020 15:57:50
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 15:57:50

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:45:09
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T18:24:10', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'fa6a6eb8-5e2f-4017-8743-b9b2b51048cf'	System	20 Aug 2020 23:24:53
User entered 'None (1)'	System	20 Aug 2020 23:24:53

FDA-CBER-2022-1614-3171755

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:45:09
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T18:24:19', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'fa6a6eb8-5e2f-4017-8743-b9b2b51048cf'	System	20 Aug 2020 23:24:53
User entered 'No (N)'	System	20 Aug 2020 23:24:53

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:45:09
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T18:24:27', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'fa6a6eb8-5e2f-4017-8743-b9b2b51048cf'	System	20 Aug 2020 23:24:53
User entered 'No (N)'	System	20 Aug 2020 23:24:53

FDA-CBER-2022-1614-3171757

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:45:09
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T18:24:39', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'fa6a6eb8-5e2f-4017-8743-b9b2b51048cf'	System	20 Aug 2020 23:24:53
User entered 'None (1)'	System	20 Aug 2020 23:24:53

FDA-CBER-2022-1614-3171758

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:45:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T18:24:50', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'fa6a6eb8-5e2f-4017-8743-b9b2b51048cf'	System	20 Aug 2020 23:24:53
User entered '20 Aug 2020 18:24'	System	20 Aug 2020 23:24:53

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:45:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '20 Aug 2020 14:31'	System	20 Aug 2020 15:57:50

FDA-CBER-2022-1614-3171760

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:45:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 15:57:50

FDA-CBER-2022-1614-3171761

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:45:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
Data entry locked.	System	20 Aug 2020 15:57:50
User entered 'Day 2'	System	20 Aug 2020 15:57:50

FDA-CBER-2022-1614-3171762

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:45:09
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-21T20:38:40', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'c2ab5fc1-5f62-4d4e-abea-d3928c2530c7'	System	22 Aug 2020 01:39:09
User entered 'Does not interfere with activity (2)'	System	22 Aug 2020 01:39:09

FDA-CBER-2022-1614-3171763

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:45:09
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-21T20:38:46', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'c2ab5fc1-5f62-4d4e-abea-d3928c2530c7'	System	22 Aug 2020 01:39:09
User entered 'No (N)'	System	22 Aug 2020 01:39:09

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:45:09
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-21T20:38:51', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'c2ab5fc1-5f62-4d4e-abea-d3928c2530c7'	System	22 Aug 2020 01:39:09
User entered 'No (N)'	System	22 Aug 2020 01:39:09

FDA-CBER-2022-1614-3171765

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:45:09
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-21T20:38:59', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'c2ab5fc1-5f62-4d4e-abea-d3928c2530c7'	System	22 Aug 2020 01:39:09
User entered 'None (1)'	System	22 Aug 2020 01:39:09

FDA-CBER-2022-1614-3171766

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:45:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-21T20:39:04', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'c2ab5fc1-5f62-4d4e-abea-d3928c2530c7'	System	22 Aug 2020 01:39:09
User entered '21 Aug 2020 20:39'	System	22 Aug 2020 01:39:09

FDA-CBER-2022-1614-3171767

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:45:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 15:57:50

FDA-CBER-2022-1614-3171768

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:45:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 15:57:50

FDA-CBER-2022-1614-3171769

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:45:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
Data entry locked.	System	20 Aug 2020 15:57:50
User entered 'Day 3'	System	20 Aug 2020 15:57:50

FDA-CBER-2022-1614-3171770

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:45:09
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-22T19:36:05', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '741ce6cd-97d1-43e3-acf8-f9a866a3b422'	System	23 Aug 2020 00:36:35
User entered 'Does not interfere with activity (2)'	System	23 Aug 2020 00:36:35

FDA-CBER-2022-1614-3171771

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:45:09
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-22T19:36:10', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '741ce6cd-97d1-43e3-acf8-f9a866a3b422'	System	23 Aug 2020 00:36:35
User entered 'No (N)'	System	23 Aug 2020 00:36:35

FDA-CBER-2022-1614-3171772

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:45:09
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-22T19:36:15', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '741ce6cd-97d1-43e3-acf8-f9a866a3b422'	System	23 Aug 2020 00:36:35
User entered 'No (N)'	System	23 Aug 2020 00:36:35

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:45:09
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-22T19:36:25', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '741ce6cd-97d1-43e3-acf8-f9a866a3b422'	System	23 Aug 2020 00:36:35
User entered 'None (1)'	System	23 Aug 2020 00:36:35

FDA-CBER-2022-1614-3171774

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:45:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-22T19:36:30', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '741ce6cd-97d1-43e3-acf8-f9a866a3b422'	System	23 Aug 2020 00:36:35
User entered '22 Aug 2020 19:36'	System	23 Aug 2020 00:36:35

FDA-CBER-2022-1614-3171775

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:45:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 15:57:50

FDA-CBER-2022-1614-3171776

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:45:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 15:57:50

FDA-CBER-2022-1614-3171777

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:45:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
Data entry locked.	System	20 Aug 2020 15:57:50
User entered 'Day 4'	System	20 Aug 2020 15:57:50

FDA-CBER-2022-1614-3171778

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:45:09
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-23T21:23:57', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '335172f4-4a5f-4534-a3ff-f40be8c38849'	System	24 Aug 2020 02:24:45
User entered 'None (1)'	System	24 Aug 2020 02:24:45

FDA-CBER-2022-1614-3171779

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:45:09
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-23T21:24:02', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '335172f4-4a5f-4534-a3ff-f40be8c38849'	System	24 Aug 2020 02:24:45
User entered 'No (N)'	System	24 Aug 2020 02:24:45

FDA-CBER-2022-1614-3171780

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:45:09
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-23T21:24:08', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '335172f4-4a5f-4534-a3ff-f40be8c38849'	System	24 Aug 2020 02:24:45
User entered 'No (N)'	System	24 Aug 2020 02:24:45

FDA-CBER-2022-1614-3171781

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:45:09
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-23T21:24:28', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '335172f4-4a5f-4534-a3ff-f40be8c38849'	System	24 Aug 2020 02:24:45
User entered 'None (1)'	System	24 Aug 2020 02:24:45

FDA-CBER-2022-1614-3171782

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:45:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-23T21:24:33', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '335172f4-4a5f-4534-a3ff-f40be8c38849'	System	24 Aug 2020 02:24:45
User entered '23 Aug 2020 21:24'	System	24 Aug 2020 02:24:45

FDA-CBER-2022-1614-3171783

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:45:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 15:57:50

FDA-CBER-2022-1614-3171784

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:45:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 15:57:50

FDA-CBER-2022-1614-3171785

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:45:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
Data entry locked.	System	20 Aug 2020 15:57:50
User entered 'Day 5'	System	20 Aug 2020 15:57:50

FDA-CBER-2022-1614-3171786

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:45:09
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-24T20:35:20', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '1bbfa4aa-e5c9-4385-a871-db07de8a21df'	System	25 Aug 2020 01:36:32
User entered 'None (1)'	System	25 Aug 2020 01:36:32

FDA-CBER-2022-1614-3171787

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:45:09
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-24T20:35:55', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '1bbfa4aa-e5c9-4385-a871-db07de8a21df'	System	25 Aug 2020 01:36:32
User entered 'No (N)'	System	25 Aug 2020 01:36:32

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:45:09
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-24T20:36:04', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '1bbfa4aa-e5c9-4385-a871-db07de8a21df'	System	25 Aug 2020 01:36:32
User entered 'No (N)'	System	25 Aug 2020 01:36:32

FDA-CBER-2022-1614-3171789

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:45:09
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-24T20:36:23', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '1bbfa4aa-e5c9-4385-a871-db07de8a21df'	System	25 Aug 2020 01:36:32
User entered 'None (1)'	System	25 Aug 2020 01:36:32

FDA-CBER-2022-1614-3171790

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:45:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-24T20:36:28', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '1bbfa4aa-e5c9-4385-a871-db07de8a21df'	System	25 Aug 2020 01:36:32
User entered '24 Aug 2020 20:36'	System	25 Aug 2020 01:36:32

FDA-CBER-2022-1614-3171791

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:45:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 15:57:50

FDA-CBER-2022-1614-3171792

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:45:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 15:57:50

FDA-CBER-2022-1614-3171793

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:45:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
Data entry locked.	System	20 Aug 2020 15:57:50
User entered 'Day 6'	System	20 Aug 2020 15:57:50

FDA-CBER-2022-1614-3171794

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:45:09
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-25T20:06:53', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'd0f048c1-59c2-47a6-b956-bc47bfca6ea5'	System	26 Aug 2020 01:07:19
User entered 'None (1)'	System	26 Aug 2020 01:07:19

FDA-CBER-2022-1614-3171795

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:45:09
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-25T20:06:58', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'd0f048c1-59c2-47a6-b956-bc47bfca6ea5'	System	26 Aug 2020 01:07:19
User entered 'No (N)'	System	26 Aug 2020 01:07:19

FDA-CBER-2022-1614-3171796

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:45:09
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-25T20:07:04', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'd0f048c1-59c2-47a6-b956-bc47bfca6ea5'	System	26 Aug 2020 01:07:19
User entered 'No (N)'	System	26 Aug 2020 01:07:19

FDA-CBER-2022-1614-3171797

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:45:09
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-25T20:07:13', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'd0f048c1-59c2-47a6-b956-bc47bfca6ea5'	System	26 Aug 2020 01:07:19
User entered 'None (1)'	System	26 Aug 2020 01:07:19

FDA-CBER-2022-1614-3171798

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:45:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-25T20:07:18', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'd0f048c1-59c2-47a6-b956-bc47bfca6ea5'	System	26 Aug 2020 01:07:19
User entered '25 Aug 2020 20:07'	System	26 Aug 2020 01:07:19

FDA-CBER-2022-1614-3171799

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:45:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 15:57:50

FDA-CBER-2022-1614-3171800

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:45:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 15:57:50

FDA-CBER-2022-1614-3171801

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:45:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
Data entry locked.	System	20 Aug 2020 15:57:50
User entered 'Day 7'	System	20 Aug 2020 15:57:50

FDA-CBER-2022-1614-3171802

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:45:09
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-26T19:19:50', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '63e77767-3670-4106-9432-7ff97ed36750'	System	27 Aug 2020 00:20:18
User entered 'None (1)'	System	27 Aug 2020 00:20:18

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:45:09
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-26T19:19:55', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '63e77767-3670-4106-9432-7ff97ed36750'	System	27 Aug 2020 00:20:18
User entered 'No (N)'	System	27 Aug 2020 00:20:18

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:45:09
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-26T19:20:01', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '63e77767-3670-4106-9432-7ff97ed36750'	System	27 Aug 2020 00:20:18
User entered 'No (N)'	System	27 Aug 2020 00:20:18

FDA-CBER-2022-1614-3171805

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:45:09
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-26T19:20:06', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '63e77767-3670-4106-9432-7ff97ed36750'	System	27 Aug 2020 00:20:18
User entered 'None (1)'	System	27 Aug 2020 00:20:18

FDA-CBER-2022-1614-3171806

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:45:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-26T19:20:15', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '63e77767-3670-4106-9432-7ff97ed36750'	System	27 Aug 2020 00:20:18
User entered '26 Aug 2020 19:20'	System	27 Aug 2020 00:20:18

FDA-CBER-2022-1614-3171807

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:45:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 15:57:50

FDA-CBER-2022-1614-3171808

US3752173
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:45:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 15:57:50

FDA-CBER-2022-1614-3171809

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:45:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
Data entry locked.	System	20 Aug 2020 15:57:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 15:57:50

FDA-CBER-2022-1614-3171810

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:45:09
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T11:25:24', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '524b745f-c340-440d-83a2-62b6db79168e'	System	20 Aug 2020 23:22:40
User entered 'None (0)'	System	20 Aug 2020 23:22:40

FDA-CBER-2022-1614-3171811

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:45:09
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T11:25:28', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '524b745f-c340-440d-83a2-62b6db79168e'	System	20 Aug 2020 23:22:40
User entered 'None (0)'	System	20 Aug 2020 23:22:40

FDA-CBER-2022-1614-3171812

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:45:09
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T11:25:32', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '524b745f-c340-440d-83a2-62b6db79168e'	System	20 Aug 2020 23:22:40
User entered 'None (0)'	System	20 Aug 2020 23:22:40

FDA-CBER-2022-1614-3171813

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:45:09
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T11:25:38', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '524b745f-c340-440d-83a2-62b6db79168e'	System	20 Aug 2020 23:22:40
User entered 'None (0)'	System	20 Aug 2020 23:22:40

FDA-CBER-2022-1614-3171814

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:45:09
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T11:25:42', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '524b745f-c340-440d-83a2-62b6db79168e'	System	20 Aug 2020 23:22:40
User entered 'None (0)'	System	20 Aug 2020 23:22:40

FDA-CBER-2022-1614-3171815

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:45:09
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T11:25:54', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '524b745f-c340-440d-83a2-62b6db79168e'	System	20 Aug 2020 23:22:40
User entered 'None (0)'	System	20 Aug 2020 23:22:40

FDA-CBER-2022-1614-3171816

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:45:09
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T11:26:01', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '524b745f-c340-440d-83a2-62b6db79168e'	System	20 Aug 2020 23:22:40
User entered 'No (N)'	System	20 Aug 2020 23:22:40

FDA-CBER-2022-1614-3171817

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:45:09
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T11:26:09', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '524b745f-c340-440d-83a2-62b6db79168e'	System	20 Aug 2020 23:22:40
User entered '20 Aug 2020 11:26'	System	20 Aug 2020 23:22:40

FDA-CBER-2022-1614-3171818

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:45:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '20 Aug 2020 11:06'	System	20 Aug 2020 15:57:50

FDA-CBER-2022-1614-3171819

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:45:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '20 Aug 2020 13:36'	System	20 Aug 2020 15:57:50

FDA-CBER-2022-1614-3171820

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:45:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
Data entry locked.	System	20 Aug 2020 15:57:50
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 15:57:50

FDA-CBER-2022-1614-3171821

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:45:09
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T18:25:13', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'daa04446-f9b7-4015-bb74-5f53789e8c0c'	System	20 Aug 2020 23:25:57
User entered 'None (0)'	System	20 Aug 2020 23:25:57

FDA-CBER-2022-1614-3171822

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:45:09
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T18:25:20', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'daa04446-f9b7-4015-bb74-5f53789e8c0c'	System	20 Aug 2020 23:25:57
User entered 'None (0)'	System	20 Aug 2020 23:25:57

FDA-CBER-2022-1614-3171823

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:45:09
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T18:25:26', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'daa04446-f9b7-4015-bb74-5f53789e8c0c'	System	20 Aug 2020 23:25:57
User entered 'None (0)'	System	20 Aug 2020 23:25:57

FDA-CBER-2022-1614-3171824

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:45:09
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T18:25:31', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'daa04446-f9b7-4015-bb74-5f53789e8c0c'	System	20 Aug 2020 23:25:57
User entered 'None (0)'	System	20 Aug 2020 23:25:57

FDA-CBER-2022-1614-3171825

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:45:09
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T18:25:36', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'daa04446-f9b7-4015-bb74-5f53789e8c0c'	System	20 Aug 2020 23:25:57
User entered 'None (0)'	System	20 Aug 2020 23:25:57

FDA-CBER-2022-1614-3171826

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:45:09
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T18:25:40', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'daa04446-f9b7-4015-bb74-5f53789e8c0c'	System	20 Aug 2020 23:25:57
User entered 'None (0)'	System	20 Aug 2020 23:25:57

FDA-CBER-2022-1614-3171827

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:45:09
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T18:25:48', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'daa04446-f9b7-4015-bb74-5f53789e8c0c'	System	20 Aug 2020 23:25:57
User entered 'No (N)'	System	20 Aug 2020 23:25:57

FDA-CBER-2022-1614-3171828

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:45:09
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-20T18:25:54', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'daa04446-f9b7-4015-bb74-5f53789e8c0c'	System	20 Aug 2020 23:25:57
User entered '20 Aug 2020 18:25'	System	20 Aug 2020 23:25:57

FDA-CBER-2022-1614-3171829

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:45:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '20 Aug 2020 14:31'	System	20 Aug 2020 15:57:50

FDA-CBER-2022-1614-3171830

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:45:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 15:57:50

FDA-CBER-2022-1614-3171831

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:45:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
Data entry locked.	System	20 Aug 2020 15:57:50
User entered 'Day 2'	System	20 Aug 2020 15:57:50

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:45:09
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-21T20:39:23', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'cd0195e9-17cd-4309-9a9b-264625b78e09'	System	22 Aug 2020 01:40:14
User entered 'None (0)'	System	22 Aug 2020 01:40:14

FDA-CBER-2022-1614-3171833

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:45:09
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-21T20:39:36', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'cd0195e9-17cd-4309-9a9b-264625b78e09'	System	22 Aug 2020 01:40:14
User entered 'None (0)'	System	22 Aug 2020 01:40:14

FDA-CBER-2022-1614-3171834

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:45:09
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-21T20:39:41', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'cd0195e9-17cd-4309-9a9b-264625b78e09'	System	22 Aug 2020 01:40:14
User entered 'None (0)'	System	22 Aug 2020 01:40:14

FDA-CBER-2022-1614-3171835

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:45:09
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-21T20:39:47', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'cd0195e9-17cd-4309-9a9b-264625b78e09'	System	22 Aug 2020 01:40:14
User entered 'None (0)'	System	22 Aug 2020 01:40:14

FDA-CBER-2022-1614-3171836

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:45:09
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-21T20:39:51', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'cd0195e9-17cd-4309-9a9b-264625b78e09'	System	22 Aug 2020 01:40:14
User entered 'None (0)'	System	22 Aug 2020 01:40:14

FDA-CBER-2022-1614-3171837

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:45:09
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-21T20:39:55', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'cd0195e9-17cd-4309-9a9b-264625b78e09'	System	22 Aug 2020 01:40:14
User entered 'None (0)'	System	22 Aug 2020 01:40:14

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:45:09
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-21T20:40:06', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'cd0195e9-17cd-4309-9a9b-264625b78e09'	System	22 Aug 2020 01:40:14
User entered 'No (N)'	System	22 Aug 2020 01:40:14

FDA-CBER-2022-1614-3171839

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:45:09
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-21T20:40:12', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'cd0195e9-17cd-4309-9a9b-264625b78e09'	System	22 Aug 2020 01:40:14
User entered '21 Aug 2020 20:40'	System	22 Aug 2020 01:40:14

FDA-CBER-2022-1614-3171840

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:45:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 15:57:50

FDA-CBER-2022-1614-3171841

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:45:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 15:57:50

FDA-CBER-2022-1614-3171842

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:45:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
Data entry locked.	System	20 Aug 2020 15:57:50
User entered 'Day 3'	System	20 Aug 2020 15:57:50

FDA-CBER-2022-1614-3171843

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:45:09
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-22T19:36:41', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '29a53336-b390-4652-8e9c-b2353d34d985'	System	23 Aug 2020 00:37:32
User entered 'None (0)'	System	23 Aug 2020 00:37:32

FDA-CBER-2022-1614-3171844

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:45:09
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-22T19:36:51', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '29a53336-b390-4652-8e9c-b2353d34d985'	System	23 Aug 2020 00:37:32
User entered 'None (0)'	System	23 Aug 2020 00:37:32

FDA-CBER-2022-1614-3171845

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:45:09
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-22T19:36:57', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '29a53336-b390-4652-8e9c-b2353d34d985'	System	23 Aug 2020 00:37:32
User entered 'None (0)'	System	23 Aug 2020 00:37:32

FDA-CBER-2022-1614-3171846

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:45:09
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-22T19:37:02', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '29a53336-b390-4652-8e9c-b2353d34d985'	System	23 Aug 2020 00:37:32
User entered 'None (0)'	System	23 Aug 2020 00:37:32

FDA-CBER-2022-1614-3171847

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:45:09
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-22T19:37:12', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '29a53336-b390-4652-8e9c-b2353d34d985'	System	23 Aug 2020 00:37:32
User entered 'None (0)'	System	23 Aug 2020 00:37:32

FDA-CBER-2022-1614-3171848

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:45:09
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-22T19:37:18', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '29a53336-b390-4652-8e9c-b2353d34d985'	System	23 Aug 2020 00:37:32
User entered 'None (0)'	System	23 Aug 2020 00:37:32

FDA-CBER-2022-1614-3171849

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:45:09
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-22T19:37:25', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '29a53336-b390-4652-8e9c-b2353d34d985'	System	23 Aug 2020 00:37:32
User entered 'No (N)'	System	23 Aug 2020 00:37:32

FDA-CBER-2022-1614-3171850

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:45:09
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-22T19:37:30', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '29a53336-b390-4652-8e9c-b2353d34d985'	System	23 Aug 2020 00:37:32
User entered '22 Aug 2020 19:37'	System	23 Aug 2020 00:37:32

FDA-CBER-2022-1614-3171851

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:45:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 15:57:50

FDA-CBER-2022-1614-3171852

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:45:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 15:57:50

FDA-CBER-2022-1614-3171853

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:45:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
Data entry locked.	System	20 Aug 2020 15:57:50
User entered 'Day 4'	System	20 Aug 2020 15:57:50

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:45:09
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-23T21:24:44', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '984eb8b6-5d76-4e6c-901e-4e312429eb83'	System	24 Aug 2020 02:25:59
User entered 'None (0)'	System	24 Aug 2020 02:25:59

FDA-CBER-2022-1614-3171855

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:45:09
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-23T21:24:51', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '984eb8b6-5d76-4e6c-901e-4e312429eb83'	System	24 Aug 2020 02:25:59
User entered 'None (0)'	System	24 Aug 2020 02:25:59

FDA-CBER-2022-1614-3171856

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:45:09
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-23T21:24:55', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '984eb8b6-5d76-4e6c-901e-4e312429eb83'	System	24 Aug 2020 02:25:59
User entered 'None (0)'	System	24 Aug 2020 02:25:59

FDA-CBER-2022-1614-3171857

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:45:09
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-23T21:25:03', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '984eb8b6-5d76-4e6c-901e-4e312429eb83'	System	24 Aug 2020 02:25:59
User entered 'None (0)'	System	24 Aug 2020 02:25:59

FDA-CBER-2022-1614-3171858

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:45:09
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-23T21:25:22', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '984eb8b6-5d76-4e6c-901e-4e312429eb83'	System	24 Aug 2020 02:25:59
User entered 'None (0)'	System	24 Aug 2020 02:25:59

FDA-CBER-2022-1614-3171859

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:45:09
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-23T21:25:40', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '984eb8b6-5d76-4e6c-901e-4e312429eb83'	System	24 Aug 2020 02:25:59
User entered 'None (0)'	System	24 Aug 2020 02:25:59

FDA-CBER-2022-1614-3171860

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:45:09
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-23T21:25:46', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '984eb8b6-5d76-4e6c-901e-4e312429eb83'	System	24 Aug 2020 02:25:59
User entered 'No (N)'	System	24 Aug 2020 02:25:59

FDA-CBER-2022-1614-3171861

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:45:09
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-23T21:25:56', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '984eb8b6-5d76-4e6c-901e-4e312429eb83'	System	24 Aug 2020 02:25:59
User entered '23 Aug 2020 21:25'	System	24 Aug 2020 02:25:59

FDA-CBER-2022-1614-3171862

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:45:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 15:57:50

FDA-CBER-2022-1614-3171863

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:45:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 15:57:50

FDA-CBER-2022-1614-3171864

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:45:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
Data entry locked.	System	20 Aug 2020 15:57:50
User entered 'Day 5'	System	20 Aug 2020 15:57:50

FDA-CBER-2022-1614-3171865

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:45:09
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-24T20:37:27', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '1b8fa2a8-adbf-46c6-a9ef-bcfd320ecb0c'	System	25 Aug 2020 01:38:28
User entered 'None (0)'	System	25 Aug 2020 01:38:28

FDA-CBER-2022-1614-3171866

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:45:09
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-24T20:37:08', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '1b8fa2a8-adbf-46c6-a9ef-bcfd320ecb0c'	System	25 Aug 2020 01:38:28
User entered 'No interference with activity (1)'	System	25 Aug 2020 01:38:28

FDA-CBER-2022-1614-3171867

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:45:09
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-24T20:37:32', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '1b8fa2a8-adbf-46c6-a9ef-bcfd320ecb0c'	System	25 Aug 2020 01:38:28
User entered 'None (0)'	System	25 Aug 2020 01:38:28

FDA-CBER-2022-1614-3171868

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:45:09
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-24T20:37:37', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '1b8fa2a8-adbf-46c6-a9ef-bcfd320ecb0c'	System	25 Aug 2020 01:38:28
User entered 'None (0)'	System	25 Aug 2020 01:38:28

FDA-CBER-2022-1614-3171869

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:45:09
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-24T20:37:49', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '1b8fa2a8-adbf-46c6-a9ef-bcfd320ecb0c'	System	25 Aug 2020 01:38:28
User entered 'None (0)'	System	25 Aug 2020 01:38:28

FDA-CBER-2022-1614-3171870

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:45:09
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-24T20:38:01', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '1b8fa2a8-adbf-46c6-a9ef-bcfd320ecb0c'	System	25 Aug 2020 01:38:28
User entered 'None (0)'	System	25 Aug 2020 01:38:28

FDA-CBER-2022-1614-3171871

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:45:09
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-24T20:38:11', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '1b8fa2a8-adbf-46c6-a9ef-bcfd320ecb0c'	System	25 Aug 2020 01:38:28
User entered 'No (N)'	System	25 Aug 2020 01:38:28

FDA-CBER-2022-1614-3171872

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:45:09
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-24T20:38:26', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '1b8fa2a8-adbf-46c6-a9ef-bcfd320ecb0c'	System	25 Aug 2020 01:38:28
User entered '24 Aug 2020 20:38'	System	25 Aug 2020 01:38:28

FDA-CBER-2022-1614-3171873

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:45:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 15:57:50

FDA-CBER-2022-1614-3171874

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:45:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 15:57:50

FDA-CBER-2022-1614-3171875

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:45:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
Data entry locked.	System	20 Aug 2020 15:57:50
User entered 'Day 6'	System	20 Aug 2020 15:57:50

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:45:09
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-25T20:07:27', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '6b30f034-0f65-4fe2-94b3-9a0cbc00b2ad'	System	26 Aug 2020 01:08:09
User entered 'None (0)'	System	26 Aug 2020 01:08:09

FDA-CBER-2022-1614-3171877

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:45:09
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-25T20:07:31', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '6b30f034-0f65-4fe2-94b3-9a0cbc00b2ad'	System	26 Aug 2020 01:08:09
User entered 'None (0)'	System	26 Aug 2020 01:08:09

FDA-CBER-2022-1614-3171878

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:45:09
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-25T20:07:37', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '6b30f034-0f65-4fe2-94b3-9a0cbc00b2ad'	System	26 Aug 2020 01:08:09
User entered 'None (0)'	System	26 Aug 2020 01:08:09

FDA-CBER-2022-1614-3171879

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:45:09
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-25T20:07:42', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '6b30f034-0f65-4fe2-94b3-9a0cbc00b2ad'	System	26 Aug 2020 01:08:09
User entered 'None (0)'	System	26 Aug 2020 01:08:09

FDA-CBER-2022-1614-3171880

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:45:09
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-25T20:07:48', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '6b30f034-0f65-4fe2-94b3-9a0cbc00b2ad'	System	26 Aug 2020 01:08:09
User entered 'None (0)'	System	26 Aug 2020 01:08:09

FDA-CBER-2022-1614-3171881

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:45:09
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-25T20:07:52', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '6b30f034-0f65-4fe2-94b3-9a0cbc00b2ad'	System	26 Aug 2020 01:08:09
User entered 'None (0)'	System	26 Aug 2020 01:08:09

FDA-CBER-2022-1614-3171882

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:45:09
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-25T20:07:59', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '6b30f034-0f65-4fe2-94b3-9a0cbc00b2ad'	System	26 Aug 2020 01:08:09
User entered 'No (N)'	System	26 Aug 2020 01:08:09

FDA-CBER-2022-1614-3171883

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:45:09
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-25T20:08:06', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '6b30f034-0f65-4fe2-94b3-9a0cbc00b2ad'	System	26 Aug 2020 01:08:09
User entered '25 Aug 2020 20:08'	System	26 Aug 2020 01:08:09

FDA-CBER-2022-1614-3171884

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:45:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 15:57:50

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:45:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 15:57:50

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:45:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
Data entry locked.	System	20 Aug 2020 15:57:50
User entered 'Day 7'	System	20 Aug 2020 15:57:50

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:45:09
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-26T19:20:28', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'e46e2557-5d38-4fa2-8c90-bd1ed8238576'	System	27 Aug 2020 00:21:20
User entered 'None (0)'	System	27 Aug 2020 00:21:20

FDA-CBER-2022-1614-3171888

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:45:09
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-26T19:20:37', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'e46e2557-5d38-4fa2-8c90-bd1ed8238576'	System	27 Aug 2020 00:21:20
User entered 'None (0)'	System	27 Aug 2020 00:21:20

FDA-CBER-2022-1614-3171889

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:45:09
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-26T19:20:42', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'e46e2557-5d38-4fa2-8c90-bd1ed8238576'	System	27 Aug 2020 00:21:20
User entered 'None (0)'	System	27 Aug 2020 00:21:20

FDA-CBER-2022-1614-3171890

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:45:09
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-26T19:20:50', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'e46e2557-5d38-4fa2-8c90-bd1ed8238576'	System	27 Aug 2020 00:21:20
User entered 'None (0)'	System	27 Aug 2020 00:21:20

FDA-CBER-2022-1614-3171891

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:45:09
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-26T19:20:55', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'e46e2557-5d38-4fa2-8c90-bd1ed8238576'	System	27 Aug 2020 00:21:20
User entered 'None (0)'	System	27 Aug 2020 00:21:20

FDA-CBER-2022-1614-3171892

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:45:09
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-26T19:21:07', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'e46e2557-5d38-4fa2-8c90-bd1ed8238576'	System	27 Aug 2020 00:21:20
User entered 'None (0)'	System	27 Aug 2020 00:21:20

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:45:09
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-26T19:21:14', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'e46e2557-5d38-4fa2-8c90-bd1ed8238576'	System	27 Aug 2020 00:21:20
User entered 'No (N)'	System	27 Aug 2020 00:21:20

FDA-CBER-2022-1614-3171894

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:45:09
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-08-26T19:21:18', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'e46e2557-5d38-4fa2-8c90-bd1ed8238576'	System	27 Aug 2020 00:21:20
User entered '26 Aug 2020 19:21'	System	27 Aug 2020 00:21:20

FDA-CBER-2022-1614-3171895

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:45:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 15:57:50

FDA-CBER-2022-1614-3171896

US3752173
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:45:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 15:57:50

FDA-CBER-2022-1614-3171897

US3752173
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:45:09
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:47
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	22 Oct 2020 20:12:19

US3752173
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:45:09
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:47
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User entered '28 Aug 2020'	Amanda Horn (b) (4) (b) (4)	22 Oct 2020 20:12:19

US3752173
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:45:09
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:47
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User entered 'Contact Made (CONTACT MADE)'	Amanda Horn (b) (4) (b) (4)	22 Oct 2020 20:12:19

US3752173
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:45:09
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:47
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User entered empty.	Amanda Horn (b) (4) (b) (4)	22 Oct 2020 20:12:19

US3752173
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:45:09
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:51
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:03:56

US3752173
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:45:09
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:51
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User entered '1'	System	18 Sep 2020 16:03:56

US3752173
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:45:09
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:59
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	22 Sep 2020 19:51:11

US3752173
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:45:09
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:59
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User entered '4 Sep 2020'	Amanda Horn (b) (4) (b) (4)	22 Sep 2020 19:51:11

US3752173
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:45:09
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:59
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User entered 'Contact Made (CONTACT MADE)'	Amanda Horn (b) (4) (b) (4)	22 Sep 2020 19:51:11

US3752173
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:45:09
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:10:59
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User entered empty.	Amanda Horn (b) (4) (b) (4)	22 Sep 2020 19:51:11

US3752173
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:45:09
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:11:06
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:04:09

US3752173
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:45:09
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 11:11:06
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:10:42
User entered '1'	System	18 Sep 2020 16:04:09

FDA-CBER-2022-1614-3171909

US3752173
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:45:09
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	22 Sep 2020 19:51:26

US3752173
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:45:09
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '11 Sep 2020'	Amanda Horn (b) (4) (b) (4)	22 Sep 2020 19:51:26

US3752173
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:45:09
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'Contact Made (CONTACT MADE)'	Amanda Horn (b) (4) (b) (4)	22 Sep 2020 19:51:26

US3752173
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:45:09
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered empty.	Amanda Horn (b) (4) (b) (4)	22 Sep 2020 19:51:26

US3752173
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:45:09
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:04:16

US3752173
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:45:09
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered '1'	System	18 Sep 2020 16:04:16

US3752173
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:45:09
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 15:26:05

US3752173
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:45:09
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '18 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 15:26:05

US3752173
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:45:09
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	21 Sep 2020 15:26:05

US3752173
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:45:09
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered 'VISIT2'	System	21 Sep 2020 15:26:05

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US3752173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:45:09
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	21 Sep 2020 15:26:41

US3752173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:45:09
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 15:26:41

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US3752173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:45:09
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '18 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 15:26:41

US3752173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:45:09
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '10:10'	(b) (4), (b) (6)	21 Sep 2020 15:26:41

US3752173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:45:09
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered '18 Sep 2020 10:10'	System	21 Sep 2020 15:26:41

FDA-CBER-2022-1614-3171924

US3752173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:45:09
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '98.0' F	(b) (4), (b) (6)	21 Sep 2020 15:26:41

US3752173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:45:09
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 15:27:01
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	21 Sep 2020 15:27:01
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 15:27:01
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 15:26:41

US3752173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:45:09
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 15:26:41

FDA-CBER-2022-1614-3171927

US3752173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:45:09
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 15:27:01
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	21 Sep 2020 15:27:01
User entered '64' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 15:27:01
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 15:26:41

US3752173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:45:09
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered 'bpm'	System	21 Sep 2020 15:27:01
User entered empty.	System	21 Sep 2020 15:26:41

FDA-CBER-2022-1614-3171929

US3752173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:45:09
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 15:27:01
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	21 Sep 2020 15:27:01
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 15:27:01
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 15:26:41

US3752173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:45:09
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered 'breaths/min'	System	21 Sep 2020 15:27:01
User entered empty.	System	21 Sep 2020 15:26:41

US3752173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:45:09
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 15:27:01
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	21 Sep 2020 15:27:01
User entered '132' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 15:27:01
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 15:26:41

US3752173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:45:09
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered 'mmHg'	System	21 Sep 2020 15:27:01
User entered empty.	System	21 Sep 2020 15:26:41

US3752173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:45:09
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 15:27:01
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	21 Sep 2020 15:27:01
User entered '70' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 15:27:01
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 15:26:41

US3752173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:45:09
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered 'mmHg'	System	21 Sep 2020 15:27:01
User entered empty.	System	21 Sep 2020 15:26:41

FDA-CBER-2022-1614-3171935

US3752173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:45:09
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	21 Sep 2020 15:26:41

FDA-CBER-2022-1614-3171936

US3752173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:45:09
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 15:26:41

FDA-CBER-2022-1614-3171937

US3752173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:45:09
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '18 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 15:26:41

FDA-CBER-2022-1614-3171938

US3752173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:45:09
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 15:27:39
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	21 Sep 2020 15:27:39
User entered '11:20' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 15:27:39
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 15:26:41

US3752173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:45:09
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered '18 Sep 2020 11:20'	System	21 Sep 2020 15:27:39
User entered empty.	System	21 Sep 2020 15:26:41

US3752173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:45:09
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 15:27:39
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	21 Sep 2020 15:27:39
User entered '98.0' F reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 15:27:39
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 15:26:41

US3752173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:45:09
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 15:27:39
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 15:26:41

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US3752173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:45:09
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 15:26:41

US3752173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:45:09
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 15:27:39
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	21 Sep 2020 15:27:39
User entered '66' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 15:27:39
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 15:26:41

US3752173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:45:09
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered 'bpm'	System	21 Sep 2020 15:27:39
User entered empty.	System	21 Sep 2020 15:26:41

US3752173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:45:09
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 15:27:39
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	21 Sep 2020 15:27:39
User entered '18' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 15:27:39
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 15:26:41

US3752173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:45:09
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered 'breaths/min'	System	21 Sep 2020 15:27:39
User entered empty.	System	21 Sep 2020 15:26:41

US3752173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:45:09
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 15:27:39
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	21 Sep 2020 15:27:39
User entered '140' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 15:27:39
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 15:26:41

US3752173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:45:09
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered 'mmHg'	System	21 Sep 2020 15:27:39
User entered empty.	System	21 Sep 2020 15:26:41

US3752173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:45:09
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User closed query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 15:27:39
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	21 Sep 2020 15:27:39
User entered '62' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 15:27:39
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Sep 2020 15:26:41
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 15:26:41

US3752173
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:45:09
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered 'mmHg'	System	21 Sep 2020 15:27:39
User entered empty.	System	21 Sep 2020 15:26:41

US3752173
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:45:09
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 15:27:56

US3752173
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:45:09
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '18 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 15:27:56

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US3752173
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:45:09
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User closed query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	18 Sep 2020 16:27:25
Query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' answered by data change (Site from System).	System	18 Sep 2020 16:27:25
User opened query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	18 Sep 2020 16:04:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 16:04:34

US3752173
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:45:09
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:04:34

US3752173
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:45:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:04:34

US3752173
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:45:09
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered 'MRNA-1273 OR PLACEBO'	System	18 Sep 2020 16:04:34

US3752173
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:45:09
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '18 Sep 2020'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:04:34

US3752173
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:45:09
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '11:00' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Sep 2020 16:27:25
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 16:04:34

US3752173
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:45:09
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered '18 Sep 2020 11:00'	System	18 Sep 2020 16:27:25
User entered empty.	System	18 Sep 2020 16:04:34

US3752173
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:45:09
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	18 Sep 2020 16:04:34

US3752173
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:45:09
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered 'ONCE'	System	18 Sep 2020 16:04:34

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US3752173
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:45:09
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered 'INTRAMUSCULAR'	System	18 Sep 2020 16:04:34

FDA-CBER-2022-1614-3171963

US3752173
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:45:09
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 15:28:21

US3752173
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:45:09
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '18 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 15:28:21

US3752173
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:45:09
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '10:25'	(b) (4), (b) (6)	21 Sep 2020 15:28:21

FDA-CBER-2022-1614-3171966

US3752173
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:45:09
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered '18 Sep 2020 10:25'	System	21 Sep 2020 15:28:21

US3752173
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 10 Jun 2021 09:45:09
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '18 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 15:28:37

US3752173
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:45:09
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	21 Sep 2020 15:28:37

US3752173
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:45:09
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 15:28:37

US3752173
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:45:09
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '10:23'	(b) (4), (b) (6)	21 Sep 2020 15:28:37

US3752173
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:45:09
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered '18 Sep 2020 10:23'	System	21 Sep 2020 15:28:37

US3752173
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:45:09
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	21 Sep 2020 15:28:37

US3752173
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:45:09
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'No (N)'	(b) (4), (b) (6)	21 Sep 2020 15:28:37

US3752173
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:45:09
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 15:28:37

US3752173
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:45:09
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered empty.	System	21 Sep 2020 15:28:37

FDA-CBER-2022-1614-3171976

US3752173
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:45:09
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 15:28:42

US3752173
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:45:09
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered '1'	System	21 Sep 2020 15:28:42

FDA-CBER-2022-1614-3171978

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:45:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
Data entry locked.	System	18 Sep 2020 16:27:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 16:27:25

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:45:09
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T11:30:07', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '57b8a652-76c3-4210-9910-00d9433dfbad'	System	18 Sep 2020 16:30:56
User entered 'Yes (Y)'	System	18 Sep 2020 16:30:56

FDA-CBER-2022-1614-3171980

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:45:09
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T11:29:49', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '57b8a652-76c3-4210-9910-00d9433dfbad'	System	18 Sep 2020 16:30:56
User entered '98.0'	System	18 Sep 2020 16:30:56

FDA-CBER-2022-1614-3171981

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:45:09
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T11:29:57', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '57b8a652-76c3-4210-9910-00d9433dfbad'	System	18 Sep 2020 16:30:56
User entered 'No (N)'	System	18 Sep 2020 16:30:56

FDA-CBER-2022-1614-3171982

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:45:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T11:30:23', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '57b8a652-76c3-4210-9910-00d9433dfbad'	System	18 Sep 2020 16:30:56
User entered '18 Sep 2020 11:30'	System	18 Sep 2020 16:30:56

FDA-CBER-2022-1614-3171983

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:45:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '18 Sep 2020 11:20'	System	18 Sep 2020 16:27:25

FDA-CBER-2022-1614-3171984

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:45:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '18 Sep 2020 13:50'	System	18 Sep 2020 16:27:25

FDA-CBER-2022-1614-3171985

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:45:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
Data entry locked.	System	18 Sep 2020 16:27:25
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 16:27:25

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:45:09
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T19:36:46', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '4902a994-1408-48ba-800f-afc36cb13e5e'	System	19 Sep 2020 00:37:55
User entered 'Yes (Y)'	System	19 Sep 2020 00:37:55

FDA-CBER-2022-1614-3171987

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:45:09
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T19:37:11', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '4902a994-1408-48ba-800f-afc36cb13e5e'	System	19 Sep 2020 00:37:55
User entered '97.5'	System	19 Sep 2020 00:37:55

FDA-CBER-2022-1614-3171988

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:45:09
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T19:37:38', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '4902a994-1408-48ba-800f-afc36cb13e5e'	System	19 Sep 2020 00:37:55
User entered 'No (N)'	System	19 Sep 2020 00:37:55

FDA-CBER-2022-1614-3171989

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:45:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T19:37:49', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '4902a994-1408-48ba-800f-afc36cb13e5e'	System	19 Sep 2020 00:37:55
User entered '18 Sep 2020 19:37'	System	19 Sep 2020 00:37:55

FDA-CBER-2022-1614-3171990

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:45:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '18 Sep 2020 14:45'	System	18 Sep 2020 16:27:25

FDA-CBER-2022-1614-3171991

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:45:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 16:27:25

FDA-CBER-2022-1614-3171992

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:45:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
Data entry locked.	System	18 Sep 2020 16:27:25
User entered 'Day 2'	System	18 Sep 2020 16:27:25

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:45:09
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-19T19:20:04', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '022f467a-6d3e-4c7a-ba7d-87bbec9e7e84'	System	21 Sep 2020 00:20:55
User entered 'Yes (Y)'	System	21 Sep 2020 00:20:55

FDA-CBER-2022-1614-3171994

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:45:09
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-19T19:20:22', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '022f467a-6d3e-4c7a-ba7d-87bbec9e7e84'	System	21 Sep 2020 00:20:55
User entered '99.7'	System	21 Sep 2020 00:20:55

FDA-CBER-2022-1614-3171995

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:45:09
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-19T19:20:29', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '022f467a-6d3e-4c7a-ba7d-87bbec9e7e84'	System	21 Sep 2020 00:20:55
User entered 'No (N)'	System	21 Sep 2020 00:20:55

FDA-CBER-2022-1614-3171996

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:45:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-19T19:20:41', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '022f467a-6d3e-4c7a-ba7d-87bbec9e7e84'	System	21 Sep 2020 00:20:55
User entered '19 Sep 2020 19:20'	System	21 Sep 2020 00:20:55

FDA-CBER-2022-1614-3171997

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:45:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 16:27:25

FDA-CBER-2022-1614-3171998

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:45:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 16:27:25

FDA-CBER-2022-1614-3171999

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:45:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
Data entry locked.	System	18 Sep 2020 16:27:25
User entered 'Day 3'	System	18 Sep 2020 16:27:25

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:45:09
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-20T19:17:40', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'e6f758ad-7459-4680-b580-da4d794a3329'	System	21 Sep 2020 00:20:58
User entered 'Yes (Y)'	System	21 Sep 2020 00:20:58

FDA-CBER-2022-1614-3172001

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:45:09
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-20T19:17:55', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'e6f758ad-7459-4680-b580-da4d794a3329'	System	21 Sep 2020 00:20:58
User entered '98.3'	System	21 Sep 2020 00:20:58

FDA-CBER-2022-1614-3172002

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:45:09
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-20T19:18:00', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'e6f758ad-7459-4680-b580-da4d794a3329'	System	21 Sep 2020 00:20:58
User entered 'No (N)'	System	21 Sep 2020 00:20:58

FDA-CBER-2022-1614-3172003

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:45:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-20T19:18:11', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'e6f758ad-7459-4680-b580-da4d794a3329'	System	21 Sep 2020 00:20:58
User entered '20 Sep 2020 19:18'	System	21 Sep 2020 00:20:58

FDA-CBER-2022-1614-3172004

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:45:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 16:27:25

FDA-CBER-2022-1614-3172005

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:45:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 16:27:25

FDA-CBER-2022-1614-3172006

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:45:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
Data entry locked.	System	18 Sep 2020 16:27:25
User entered 'Day 4'	System	18 Sep 2020 16:27:25

FDA-CBER-2022-1614-3172007

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:45:09
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172008

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:45:09
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172009

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:45:09
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:45:09
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172011

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:45:09
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172012

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:45:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172013

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:45:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 16:27:25

FDA-CBER-2022-1614-3172014

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:45:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 16:27:25

FDA-CBER-2022-1614-3172015

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:45:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
Data entry locked.	System	18 Sep 2020 16:27:25
User entered 'Day 5'	System	18 Sep 2020 16:27:25

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:45:09
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172017

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:45:09
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172018

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:45:09
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172019

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:45:09
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172020

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:45:09
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172021

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:45:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172022

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:45:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 16:27:25

FDA-CBER-2022-1614-3172023

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:45:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 16:27:25

FDA-CBER-2022-1614-3172024

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:45:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
Data entry locked.	System	18 Sep 2020 16:27:25
User entered 'Day 6'	System	18 Sep 2020 16:27:25

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:45:09
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172026

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:45:09
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172027

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:45:09
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172028

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:45:09
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172029

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:45:09
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:45:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172031

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:45:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 16:27:25

FDA-CBER-2022-1614-3172032

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:45:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 16:27:25

FDA-CBER-2022-1614-3172033

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:45:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
Data entry locked.	System	18 Sep 2020 16:27:25
User entered 'Day 7'	System	18 Sep 2020 16:27:25

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:45:09
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172035

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:45:09
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172036

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:45:09
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172037

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:45:09
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172038

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:45:09
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172039

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:45:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172040

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:45:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 16:27:25

FDA-CBER-2022-1614-3172041

US3752173
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:45:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 16:27:25

FDA-CBER-2022-1614-3172042

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:45:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
Data entry locked.	System	18 Sep 2020 16:27:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 16:27:25

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:45:09
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T11:31:08', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'a3376d96-1eaa-445f-b782-2962844e98fa'	System	18 Sep 2020 16:32:04
User entered 'None (1)'	System	18 Sep 2020 16:32:04

FDA-CBER-2022-1614-3172044

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:45:09
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T11:30:48', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'a3376d96-1eaa-445f-b782-2962844e98fa'	System	18 Sep 2020 16:32:04
User entered 'No (N)'	System	18 Sep 2020 16:32:04

FDA-CBER-2022-1614-3172045

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:45:09
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T11:30:55', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'a3376d96-1eaa-445f-b782-2962844e98fa'	System	18 Sep 2020 16:32:04
User entered 'No (N)'	System	18 Sep 2020 16:32:04

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:45:09
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T11:30:59', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'a3376d96-1eaa-445f-b782-2962844e98fa'	System	18 Sep 2020 16:32:04
User entered 'None (1)'	System	18 Sep 2020 16:32:04

FDA-CBER-2022-1614-3172047

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:45:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T11:31:20', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'a3376d96-1eaa-445f-b782-2962844e98fa'	System	18 Sep 2020 16:32:04
User entered '18 Sep 2020 11:31'	System	18 Sep 2020 16:32:04

FDA-CBER-2022-1614-3172048

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:45:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '18 Sep 2020 11:20'	System	18 Sep 2020 16:27:25

FDA-CBER-2022-1614-3172049

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:45:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '18 Sep 2020 13:50'	System	18 Sep 2020 16:27:25

FDA-CBER-2022-1614-3172050

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:45:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
Data entry locked.	System	18 Sep 2020 16:27:25
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 16:27:25

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:45:09
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T19:33:08', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '3eb9a963-637b-4957-8a20-8487b5a68e11'	System	19 Sep 2020 00:33:40
User entered 'None (1)'	System	19 Sep 2020 00:33:40

FDA-CBER-2022-1614-3172052

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:45:09
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T19:33:01', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '3eb9a963-637b-4957-8a20-8487b5a68e11'	System	19 Sep 2020 00:33:40
User entered 'No (N)'	System	19 Sep 2020 00:33:40

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:45:09
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T19:33:13', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '3eb9a963-637b-4957-8a20-8487b5a68e11'	System	19 Sep 2020 00:33:40
User entered 'No (N)'	System	19 Sep 2020 00:33:40

FDA-CBER-2022-1614-3172054

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:45:09
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T19:33:18', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '3eb9a963-637b-4957-8a20-8487b5a68e11'	System	19 Sep 2020 00:33:40
User entered 'None (1)'	System	19 Sep 2020 00:33:40

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:45:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T19:33:36', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '3eb9a963-637b-4957-8a20-8487b5a68e11'	System	19 Sep 2020 00:33:40
User entered '18 Sep 2020 19:33'	System	19 Sep 2020 00:33:40

FDA-CBER-2022-1614-3172056

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:45:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '18 Sep 2020 14:45'	System	18 Sep 2020 16:27:25

FDA-CBER-2022-1614-3172057

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:45:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 16:27:25

FDA-CBER-2022-1614-3172058

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:45:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
Data entry locked.	System	18 Sep 2020 16:27:25
User entered 'Day 2'	System	18 Sep 2020 16:27:25

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:45:09
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-19T19:21:07', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'b7d1338f-8d39-4d47-9048-3383e3426b92'	System	21 Sep 2020 00:20:56
User entered 'None (1)'	System	21 Sep 2020 00:20:56

FDA-CBER-2022-1614-3172060

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:45:09
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-19T19:21:13', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'b7d1338f-8d39-4d47-9048-3383e3426b92'	System	21 Sep 2020 00:20:56
User entered 'No (N)'	System	21 Sep 2020 00:20:56

FDA-CBER-2022-1614-3172061

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:45:09
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-19T19:21:18', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'b7d1338f-8d39-4d47-9048-3383e3426b92'	System	21 Sep 2020 00:20:56
User entered 'No (N)'	System	21 Sep 2020 00:20:56

FDA-CBER-2022-1614-3172062

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:45:09
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-19T19:21:28', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'b7d1338f-8d39-4d47-9048-3383e3426b92'	System	21 Sep 2020 00:20:56
User entered 'None (1)'	System	21 Sep 2020 00:20:56

FDA-CBER-2022-1614-3172063

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:45:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-19T19:21:52', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'b7d1338f-8d39-4d47-9048-3383e3426b92'	System	21 Sep 2020 00:20:56
User entered '19 Sep 2020 19:21'	System	21 Sep 2020 00:20:56

FDA-CBER-2022-1614-3172064

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:45:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 16:27:25

FDA-CBER-2022-1614-3172065

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:45:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 16:27:25

FDA-CBER-2022-1614-3172066

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:45:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
Data entry locked.	System	18 Sep 2020 16:27:25
User entered 'Day 3'	System	18 Sep 2020 16:27:25

FDA-CBER-2022-1614-3172067

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:45:09
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-20T19:18:24', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '150a7163-188a-4665-8e0a-3b9c3755519a'	System	21 Sep 2020 00:20:59
User entered 'None (1)'	System	21 Sep 2020 00:20:59

FDA-CBER-2022-1614-3172068

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:45:09
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-20T19:18:29', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '150a7163-188a-4665-8e0a-3b9c3755519a'	System	21 Sep 2020 00:20:59
User entered 'No (N)'	System	21 Sep 2020 00:20:59

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:45:09
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-20T19:18:34', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '150a7163-188a-4665-8e0a-3b9c3755519a'	System	21 Sep 2020 00:20:59
User entered 'No (N)'	System	21 Sep 2020 00:20:59

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:45:09
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-20T19:18:39', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '150a7163-188a-4665-8e0a-3b9c3755519a'	System	21 Sep 2020 00:20:59
User entered 'None (1)'	System	21 Sep 2020 00:20:59

FDA-CBER-2022-1614-3172071

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:45:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-20T19:18:44', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '150a7163-188a-4665-8e0a-3b9c3755519a'	System	21 Sep 2020 00:20:59
User entered '20 Sep 2020 19:18'	System	21 Sep 2020 00:20:59

FDA-CBER-2022-1614-3172072

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:45:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 16:27:25

FDA-CBER-2022-1614-3172073

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:45:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 16:27:25

FDA-CBER-2022-1614-3172074

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:45:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
Data entry locked.	System	18 Sep 2020 16:27:25
User entered 'Day 4'	System	18 Sep 2020 16:27:25

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:45:09
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172076

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:45:09
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172077

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:45:09
Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172078

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:45:09
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172079

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:45:09
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172080

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:45:09
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:45:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172082

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:45:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 16:27:25

FDA-CBER-2022-1614-3172083

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:45:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 16:27:25

FDA-CBER-2022-1614-3172084

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:45:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
Data entry locked.	System	18 Sep 2020 16:27:25
User entered 'Day 5'	System	18 Sep 2020 16:27:25

FDA-CBER-2022-1614-3172085

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:45:09
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172086

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:45:09
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172087

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:45:09
Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172088

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:45:09
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172089

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:45:09
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172090

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:45:09
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172091

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:45:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172092

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:45:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 16:27:25

FDA-CBER-2022-1614-3172093

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:45:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 16:27:25

FDA-CBER-2022-1614-3172094

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:45:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
Data entry locked.	System	18 Sep 2020 16:27:25
User entered 'Day 6'	System	18 Sep 2020 16:27:25

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:45:09
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172096

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:45:09
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172097

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:45:09
Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172098

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:45:09
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172099

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:45:09
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172100

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:45:09
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172101

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:45:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172102

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:45:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 16:27:25

FDA-CBER-2022-1614-3172103

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:45:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 16:27:25

FDA-CBER-2022-1614-3172104

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:45:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
Data entry locked.	System	18 Sep 2020 16:27:25
User entered 'Day 7'	System	18 Sep 2020 16:27:25

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:45:09
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172106

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:45:09
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:45:09
Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:45:09
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:45:09
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172110

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:45:09
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172111

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:45:09
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172112

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:45:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 16:27:25

US3752173
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:45:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 16:27:25

FDA-CBER-2022-1614-3172114

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:45:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
Data entry locked.	System	18 Sep 2020 16:27:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 16:27:25

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:45:09
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T11:31:28', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'cdc9c9b3-e229-4535-8498-91d1584638c5'	System	18 Sep 2020 16:32:23
User entered 'None (0)'	System	18 Sep 2020 16:32:23

FDA-CBER-2022-1614-3172116

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:45:09
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T11:31:33', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'cdc9c9b3-e229-4535-8498-91d1584638c5'	System	18 Sep 2020 16:32:23
User entered 'None (0)'	System	18 Sep 2020 16:32:23

FDA-CBER-2022-1614-3172117

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:45:09
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T11:31:40', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'cdc9c9b3-e229-4535-8498-91d1584638c5'	System	18 Sep 2020 16:32:23
User entered 'None (0)'	System	18 Sep 2020 16:32:23

FDA-CBER-2022-1614-3172118

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:45:09
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T11:31:44', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'cdc9c9b3-e229-4535-8498-91d1584638c5'	System	18 Sep 2020 16:32:23
User entered 'None (0)'	System	18 Sep 2020 16:32:23

FDA-CBER-2022-1614-3172119

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:45:09
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T11:31:48', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'cdc9c9b3-e229-4535-8498-91d1584638c5'	System	18 Sep 2020 16:32:23
User entered 'None (0)'	System	18 Sep 2020 16:32:23

FDA-CBER-2022-1614-3172120

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:45:09
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T11:31:52', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'cdc9c9b3-e229-4535-8498-91d1584638c5'	System	18 Sep 2020 16:32:23
User entered 'None (0)'	System	18 Sep 2020 16:32:23

FDA-CBER-2022-1614-3172121

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:45:09
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T11:31:57', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'cdc9c9b3-e229-4535-8498-91d1584638c5'	System	18 Sep 2020 16:32:23
User entered 'No (N)'	System	18 Sep 2020 16:32:23

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:45:09
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T11:32:01', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: 'cdc9c9b3-e229-4535-8498-91d1584638c5'	System	18 Sep 2020 16:32:23
User entered '18 Sep 2020 11:32'	System	18 Sep 2020 16:32:23

FDA-CBER-2022-1614-3172123

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:45:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '18 Sep 2020 11:20'	System	18 Sep 2020 16:27:25

FDA-CBER-2022-1614-3172124

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:45:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '18 Sep 2020 13:50'	System	18 Sep 2020 16:27:25

FDA-CBER-2022-1614-3172125

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:45:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
Data entry locked.	System	18 Sep 2020 16:27:25
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 16:27:25

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:45:09
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T19:38:02', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '748b9202-cfed-4dd1-9232-80f93f716bda'	System	19 Sep 2020 00:38:41
User entered 'None (0)'	System	19 Sep 2020 00:38:41

FDA-CBER-2022-1614-3172127

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:45:09
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T19:38:07', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '748b9202-cfed-4dd1-9232-80f93f716bda'	System	19 Sep 2020 00:38:41
User entered 'None (0)'	System	19 Sep 2020 00:38:41

FDA-CBER-2022-1614-3172128

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:45:09
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T19:38:11', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '748b9202-cfed-4dd1-9232-80f93f716bda'	System	19 Sep 2020 00:38:41
User entered 'None (0)'	System	19 Sep 2020 00:38:41

FDA-CBER-2022-1614-3172129

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:45:09
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T19:38:16', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '748b9202-cfed-4dd1-9232-80f93f716bda'	System	19 Sep 2020 00:38:41
User entered 'None (0)'	System	19 Sep 2020 00:38:41

FDA-CBER-2022-1614-3172130

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:45:09
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T19:38:20', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '748b9202-cfed-4dd1-9232-80f93f716bda'	System	19 Sep 2020 00:38:41
User entered 'None (0)'	System	19 Sep 2020 00:38:41

FDA-CBER-2022-1614-3172131

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:45:09
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T19:38:25', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '748b9202-cfed-4dd1-9232-80f93f716bda'	System	19 Sep 2020 00:38:41
User entered 'None (0)'	System	19 Sep 2020 00:38:41

FDA-CBER-2022-1614-3172132

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:45:09
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T19:38:31', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '748b9202-cfed-4dd1-9232-80f93f716bda'	System	19 Sep 2020 00:38:41
User entered 'No (N)'	System	19 Sep 2020 00:38:41

FDA-CBER-2022-1614-3172133

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:45:09
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-18T19:38:36', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '748b9202-cfed-4dd1-9232-80f93f716bda'	System	19 Sep 2020 00:38:41
User entered '18 Sep 2020 19:38'	System	19 Sep 2020 00:38:41

FDA-CBER-2022-1614-3172134

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:45:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '18 Sep 2020 14:45'	System	18 Sep 2020 16:27:25

FDA-CBER-2022-1614-3172135

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:45:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 16:27:25

FDA-CBER-2022-1614-3172136

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:45:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
Data entry locked.	System	18 Sep 2020 16:27:25
User entered 'Day 2'	System	18 Sep 2020 16:27:25

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:45:09
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-19T19:22:06', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '74d0887a-74ca-42ba-9b98-f68439b8a97e'	System	21 Sep 2020 00:20:56
User entered 'None (0)'	System	21 Sep 2020 00:20:56

FDA-CBER-2022-1614-3172138

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:45:09
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-19T19:22:12', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '74d0887a-74ca-42ba-9b98-f68439b8a97e'	System	21 Sep 2020 00:20:56
User entered 'None (0)'	System	21 Sep 2020 00:20:56

FDA-CBER-2022-1614-3172139

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:45:09
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-19T19:22:22', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '74d0887a-74ca-42ba-9b98-f68439b8a97e'	System	21 Sep 2020 00:20:56
User entered 'None (0)'	System	21 Sep 2020 00:20:56

FDA-CBER-2022-1614-3172140

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:45:09
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-19T19:22:31', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '74d0887a-74ca-42ba-9b98-f68439b8a97e'	System	21 Sep 2020 00:20:56
User entered 'No interference with activity (1)'	System	21 Sep 2020 00:20:56

FDA-CBER-2022-1614-3172141

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:45:09
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-19T19:22:55', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '74d0887a-74ca-42ba-9b98-f68439b8a97e'	System	21 Sep 2020 00:20:56
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	21 Sep 2020 00:20:56

FDA-CBER-2022-1614-3172142

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:45:09
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-19T19:23:07', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '74d0887a-74ca-42ba-9b98-f68439b8a97e'	System	21 Sep 2020 00:20:56
User entered 'No interference with activity (1)'	System	21 Sep 2020 00:20:56

FDA-CBER-2022-1614-3172143

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:45:09
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-19T19:23:18', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '74d0887a-74ca-42ba-9b98-f68439b8a97e'	System	21 Sep 2020 00:20:56
User entered 'No (N)'	System	21 Sep 2020 00:20:56

FDA-CBER-2022-1614-3172144

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:45:09
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-19T19:23:24', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '74d0887a-74ca-42ba-9b98-f68439b8a97e'	System	21 Sep 2020 00:20:56
User entered '19 Sep 2020 19:23'	System	21 Sep 2020 00:20:56

FDA-CBER-2022-1614-3172145

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:45:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 16:27:25

FDA-CBER-2022-1614-3172146

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:45:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 16:27:25

FDA-CBER-2022-1614-3172147

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:45:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
Data entry locked.	System	18 Sep 2020 16:27:25
User entered 'Day 3'	System	18 Sep 2020 16:27:25

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:45:09
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-20T19:18:53', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '508183c5-7451-4176-b0b3-5d8c51e95db1'	System	21 Sep 2020 00:20:59
User entered 'None (0)'	System	21 Sep 2020 00:20:59

FDA-CBER-2022-1614-3172149

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:45:09
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-20T19:19:01', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '508183c5-7451-4176-b0b3-5d8c51e95db1'	System	21 Sep 2020 00:20:59
User entered 'None (0)'	System	21 Sep 2020 00:20:59

FDA-CBER-2022-1614-3172150

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:45:09
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-20T19:19:07', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '508183c5-7451-4176-b0b3-5d8c51e95db1'	System	21 Sep 2020 00:20:59
User entered 'None (0)'	System	21 Sep 2020 00:20:59

FDA-CBER-2022-1614-3172151

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:45:09
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-20T19:19:12', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '508183c5-7451-4176-b0b3-5d8c51e95db1'	System	21 Sep 2020 00:20:59
User entered 'None (0)'	System	21 Sep 2020 00:20:59

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:45:09
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-20T19:19:41', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '508183c5-7451-4176-b0b3-5d8c51e95db1'	System	21 Sep 2020 00:20:59
User entered 'None (0)'	System	21 Sep 2020 00:20:59

FDA-CBER-2022-1614-3172153

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:45:09
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-20T19:19:48', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '508183c5-7451-4176-b0b3-5d8c51e95db1'	System	21 Sep 2020 00:20:59
User entered 'None (0)'	System	21 Sep 2020 00:20:59

FDA-CBER-2022-1614-3172154

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:45:09
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-20T19:19:53', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '508183c5-7451-4176-b0b3-5d8c51e95db1'	System	21 Sep 2020 00:20:59
User entered 'No (N)'	System	21 Sep 2020 00:20:59

FDA-CBER-2022-1614-3172155

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:45:09
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (77A84B5A-1B63-414C-BE36-E170501507C0)', Time: '2020-09-20T19:19:59', User OID: 'PatientReportedOutcome (US3752173)', ODM File OID: '508183c5-7451-4176-b0b3-5d8c51e95db1'	System	21 Sep 2020 00:20:59
User entered '20 Sep 2020 19:19'	System	21 Sep 2020 00:20:59

FDA-CBER-2022-1614-3172156

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:45:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 16:27:25

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:45:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 16:27:25

FDA-CBER-2022-1614-3172158

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:45:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
Data entry locked.	System	18 Sep 2020 16:27:25
User entered 'Day 4'	System	18 Sep 2020 16:27:25

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:45:09
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172160

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:45:09
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172161

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:45:09
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172162

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:45:09
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172163

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:45:09
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172164

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:45:09
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172165

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:45:09
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:45:09
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172167

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:45:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 16:27:25

FDA-CBER-2022-1614-3172168

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:45:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 16:27:25

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:45:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
Data entry locked.	System	18 Sep 2020 16:27:25
User entered 'Day 5'	System	18 Sep 2020 16:27:25

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:45:09
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172171

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:45:09
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172172

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:45:09
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172173

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:45:09
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172174

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:45:09
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172175

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:45:09
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172176

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:45:09
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172177

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:45:09
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172178

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:45:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 16:27:25

FDA-CBER-2022-1614-3172179

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:45:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 16:27:25

FDA-CBER-2022-1614-3172180

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:45:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
Data entry locked.	System	18 Sep 2020 16:27:25
User entered 'Day 6'	System	18 Sep 2020 16:27:25

FDA-CBER-2022-1614-3172181

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:45:09
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172182

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:45:09
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172183

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:45:09
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172184

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:45:09
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:45:09
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172186

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:45:09
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172187

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:45:09
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172188

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:45:09
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172189

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:45:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 16:27:25

FDA-CBER-2022-1614-3172190

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:45:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 16:27:25

FDA-CBER-2022-1614-3172191

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:45:09
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
Data entry locked.	System	18 Sep 2020 16:27:25
User entered 'Day 7'	System	18 Sep 2020 16:27:25

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:45:09
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172193

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:45:09
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172194

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:45:09
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172195

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:45:09
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172196

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:45:09
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172197

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:45:09
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172198

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:45:09
Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:45:09
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52

FDA-CBER-2022-1614-3172200

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:45:09
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 16:27:25

FDA-CBER-2022-1614-3172201

US3752173
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:45:09
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:48:52
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 16:27:25

FDA-CBER-2022-1614-3172202

US3752173
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:45:09
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 14:26:08

FDA-CBER-2022-1614-3172203

US3752173
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:45:09
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '25 Sep 2020'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 14:26:08

US3752173
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:45:09
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	05 Oct 2020 14:26:08

US3752173
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:45:09
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 14:26:08

FDA-CBER-2022-1614-3172206

US3752173
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:45:09
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 17:55:21

US3752173
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:45:09
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered '1'	System	09 Oct 2020 17:55:21

FDA-CBER-2022-1614-3172208

US3752173
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:45:09
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 19:15:17

US3752173
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:45:09
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '2 Oct 2020'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 19:15:17

US3752173
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:45:09
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'Contact Made (CONTACT MADE)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 19:15:17

US3752173
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:45:09
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 19:15:17

US3752173
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:45:09
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 17:55:31

US3752173
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:45:09
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered '1'	System	09 Oct 2020 17:55:31

US3752173
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:45:09
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 17:55:46

US3752173
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:45:09
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '9 Oct 2020'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 17:55:46

US3752173
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:45:09
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	09 Oct 2020 17:55:46

FDA-CBER-2022-1614-3172217

US3752173
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:45:09
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Oct 2020 17:55:46

FDA-CBER-2022-1614-3172218

US3752173
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:45:09
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User entered 'Yes (Y)'	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 16:07:22

US3752173
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:45:09
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered '1'	System	23 Oct 2020 16:07:22

US3752173
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:45:09
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User entered 'Yes (Y)'	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 16:07:37

FDA-CBER-2022-1614-3172221

US3752173
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:45:09
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User entered '23 Oct 2020'	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 16:07:37

FDA-CBER-2022-1614-3172222

US3752173
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:45:09
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User entered 'Clinic (Clinic)'	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 16:07:37

FDA-CBER-2022-1614-3172223

US3752173
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:45:09
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered 'VISIT3'	System	23 Oct 2020 16:07:37

FDA-CBER-2022-1614-3172224

US3752173
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:45:09
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User entered 'Yes (Y)'	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 16:08:12

US3752173
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:45:09
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User entered '23 Oct 2020'	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 16:08:12

FDA-CBER-2022-1614-3172226

US3752173
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:45:09
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User entered '10:35'	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 16:08:12

US3752173
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:45:09
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered '23 Oct 2020 10:35'	System	23 Oct 2020 16:08:12

FDA-CBER-2022-1614-3172228

US3752173
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:45:09
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User entered '97.2' F	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 16:08:12

FDA-CBER-2022-1614-3172229

US3752173
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:45:09
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User entered 'Oral (Oral)'	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 16:08:12

US3752173
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:45:09
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User entered empty.	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 16:08:12

FDA-CBER-2022-1614-3172231

US3752173
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:45:09
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User entered '68'	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 16:08:12

FDA-CBER-2022-1614-3172232

US3752173
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:45:09
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered 'bpm'	System	23 Oct 2020 16:08:12

FDA-CBER-2022-1614-3172233

US3752173
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:45:09
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User entered '16'	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 16:08:12

FDA-CBER-2022-1614-3172234

US3752173
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:45:09
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered 'breaths/min'	System	23 Oct 2020 16:08:12

FDA-CBER-2022-1614-3172235

US3752173
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:45:09
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User entered '118'	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 16:08:12

US3752173
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:45:09
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered 'mmHg'	System	23 Oct 2020 16:08:12

FDA-CBER-2022-1614-3172237

US3752173
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:45:09
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 12:02:02
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'PI reviewed vitals- no abnormalities and NCS ' (Site from System).	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 16:09:27
User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	23 Oct 2020 16:08:12
User entered '58'	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 16:08:12

US3752173
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:45:09
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered 'mmHg'	System	23 Oct 2020 16:08:12

FDA-CBER-2022-1614-3172239

US3752173
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:45:09
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12

FDA-CBER-2022-1614-3172240

US3752173
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:45:09
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12

FDA-CBER-2022-1614-3172241

US3752173
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:45:09
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User entered 'Yes (Y)'	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 16:10:37

US3752173
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:45:09
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User entered '23 Oct 2020'	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 16:10:37

FDA-CBER-2022-1614-3172243

US3752173
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:45:09
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User entered 'Yes (Y)'	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 16:11:07

FDA-CBER-2022-1614-3172244

US3752173
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:45:09
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User entered '23 Oct 2020'	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 16:11:07

US3752173
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:45:09
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User entered '10:45'	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 16:11:07

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US3752173
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:45:09
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered '23 Oct 2020 10:45'	System	23 Oct 2020 16:11:07

FDA-CBER-2022-1614-3172247

US3752173
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:45:09
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User entered 'Yes (Y)'	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 16:11:12

FDA-CBER-2022-1614-3172248

US3752173
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:45:09
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered '1'	System	23 Oct 2020 16:11:12

US3752173
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:45:09
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	23 Apr 2021 14:51:23
User closed query 'Per CDM: please confirm visit was not conducted, or otherwise clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Apr 2021 17:05:25
Query 'Per CDM: please confirm visit was not conducted, or otherwise clarify.' answered with 'UPDATED TO "NO". PATIENT PASSED AWAY. ' (Site from DM).	Haylee Rowe (b) (4) (b) (4)	21 Apr 2021 18:44:09
Signature has been broken.	Haylee Rowe (b) (4) (b) (4)	21 Apr 2021 18:43:38
User entered 'No (N)' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	21 Apr 2021 18:43:38
User opened query 'Per CDM: please confirm visit was not conducted, or otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 18:35:43
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	03 Dec 2020 07:56:03
Query 'Data is required. Please complete.' answered with 'DATA ENTRY ERROR' (Site from System).	Amanda Horn (b) (4) (b) (4)	18 Nov 2020 16:06:21
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 16:06:14
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	18 Nov 2020 16:06:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Nov 2020 17:27:49

US3752173
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:45:09
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User closed query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	18 Nov 2020 16:06:14
Query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	18 Nov 2020 16:06:14
User closed query 'Date of Contact or Contact Attempt is after Date of Death. Please review and reconcile.' (Site from System).	System	18 Nov 2020 16:06:14
User closed query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	18 Nov 2020 16:06:14
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	18 Nov 2020 16:06:14
User opened query 'Date of Contact or Contact Attempt is after Date of Death. Please review and reconcile.' (Site from System).	System	12 Nov 2020 16:53:35
User opened query 'Date of Contact or Contact Attempt is after Assessment Date of study discontinuation/completion on the End of Study/Study Discontinuation form. Please review and provide any needed correction.' (Site from System).	System	12 Nov 2020 16:53:35
User opened query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	09 Nov 2020 17:27:49
User entered '9 Nov 2020'	(b) (4), (b) (6)	09 Nov 2020 17:27:49

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US3752173
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:45:09
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	18 Nov 2020 16:06:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	09 Nov 2020 17:27:49

US3752173
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:45:09
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:27:49

US3752173
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:45:09
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	22 Apr 2021 15:22:09
Signature has been broken.	Haylee Rowe (b) (4) (b) (4)	21 Apr 2021 18:43:54
User entered 'No (N)' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	21 Apr 2021 18:43:54
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Nov 2020 17:28:03

US3752173
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:45:09
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered empty.	System	21 Apr 2021 18:43:54
User entered '1'	System	09 Nov 2020 17:28:03

US3752173
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:45:09
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User closed query 'Was Contact Attempted? = No and ‘Date of Contact or Contact Attempt’ or ‘ Please select one status for the follow-up contact’ is provided. Please review and reconcile.' (Site from System).	(b) (4) System	12 Nov 2020 20:20:49
User opened query 'Was Contact Attempted? = No and ‘Date of Contact or Contact Attempt’ or ‘ Please select one status for the follow-up contact’ is provided. Please review and reconcile.' (Site from System).	System	12 Nov 2020 20:17:07
User entered 'No (N)'	(b) (4), (b) (6)	12 Nov 2020 20:17:07

US3752173
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:45:09
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:17:07

US3752173
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:45:09
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:20:49
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	12 Nov 2020 20:17:07

US3752173
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:45:09
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'Early Termination due to death'	(b) (4), (b) (6)	12 Nov 2020 20:17:07

US3752173
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:45:09
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'No (N)'	(b) (4), (b) (6)	12 Nov 2020 20:22:18

US3752173
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:45:09
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User entered empty.	System	12 Nov 2020 20:22:18

US3752173
Folder: Covid-19 Assessment (1)
Form: COVID-19 Contact
Generated On: 10 Jun 2021 09:45:09
Date of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	02 Dec 2020 23:33:22
Query 'Data is required. Please complete.' answered with 'This was not completed, subject passed away' (Site from System).	Lauren Evans (b) (4)	13 Nov 2020 14:44:36
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 20:23:27
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 20:23:27

US3752173
Folder: Covid-19 Assessment (1)
Form: COVID-19 Contact
Generated On: 10 Jun 2021 09:45:09
Time of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	02 Dec 2020 23:33:24
Query 'Data is required. Please complete.' answered with 'This was not completed, subject passed away' (Site from System).	Lauren Evans (b) (4)	13 Nov 2020 14:44:38
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 20:23:27
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 20:23:27

US3752173
Folder: Covid-19 Assessment (1)
Form: COVID-19 Contact
Generated On: 10 Jun 2021 09:45:09
Date and Time of Contact (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User entered empty.	System	12 Nov 2020 20:23:27

US3752173
Folder: Covid-19 Assessment (1)
Form: COVID-19 Contact
Generated On: 10 Jun 2021 09:45:09
Type of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	02 Dec 2020 23:33:25
Query 'Data is required. Please complete.' answered with 'This was not completed, subject passed away' (Site from System).	Lauren Evans (b) (4)	13 Nov 2020 14:44:40
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 20:23:27
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 20:23:27

US3752173
Folder: Covid-19 Assessment (1)
Form: COVID-19 Contact
Generated On: 10 Jun 2021 09:45:09
Has the subject reported symptoms of SARS-COV-2?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:33:27
Query 'Data is required. Please complete.' answered with 'This was not completed, subject passed away' (Site from System).	Lauren Evans (b) (4)	13 Nov 2020 14:44:42
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 20:23:27
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 20:23:27

US3752173
Folder: Covid-19 Assessment (1)
Form: Generate Next COVID-19 Assessment
Generated On: 10 Jun 2021 09:45:09
Generate Next COVID-19 Assessment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:24:16

US3752173
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 10 Jun 2021 09:45:09
Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:43:47
User entered 'Yes (Y)' reason for change: New Information	Lauren Evans (b) (4)	02 Nov 2020 14:50:47
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:12:10

US3752173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:45:09
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:44:09
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 13:08:52
User entered 'USA-US113-2020-mRNA-1273-P301000007'	System	03 Nov 2020 13:08:49
User entered 'New'	(b) (4), (b) (6)	03 Nov 2020 13:08:49

US3752173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:45:09
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:44:11
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Myocardial infarction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Nov 2020 07:11:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Nov 2020 07:11:55
Data point term sent to Coder	System	02 Nov 2020 14:54:21
User entered 'Myocardial Infarction'	Lauren Evans (b) (4)	02 Nov 2020 14:53:23

US3752173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:45:09
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:44:14
User entered 'Yes (Y)'	Lauren Evans (b) (4)	02 Nov 2020 14:53:23

US3752173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:45:09
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:44:16
User entered 'No (N)'	Lauren Evans (b) (4)	02 Nov 2020 14:53:23

US3752173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:45:09
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:44:19
User entered 'No (N)'	Lauren Evans (b) (4)	02 Nov 2020 14:53:23

US3752173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:45:09
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:44:23
User entered '01 Nov 2020'	Lauren Evans (b) (4)	02 Nov 2020 14:53:23

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US3752173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:45:09
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:44:25
User entered empty.	Lauren Evans (b) (4)	02 Nov 2020 14:53:23

US3752173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:45:09
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User entered empty.	System	02 Nov 2020 14:53:23

FDA-CBER-2022-1614-3172276

US3752173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:45:09
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:44:27
User entered 'No (N)'	Lauren Evans (b) (4)	02 Nov 2020 14:53:23

FDA-CBER-2022-1614-3172277

US3752173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:45:09
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:44:29
User entered '01 Nov 2020'	Lauren Evans (b) (4)	02 Nov 2020 14:53:23

FDA-CBER-2022-1614-3172278

US3752173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:45:09
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:44:32
User entered empty.	Lauren Evans (b) (4)	02 Nov 2020 14:53:23

US3752173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:45:09
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User entered empty.	System	02 Nov 2020 14:53:23

US3752173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:45:09
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:44:35
User entered 'Grade 4 (Grade 4)'	Lauren Evans (b) (4)	02 Nov 2020 14:53:23

US3752173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:45:09
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:44:36
User entered 'Yes (Y)'	Lauren Evans (b) (4)	02 Nov 2020 14:53:23

US3752173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:45:09
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:44:39
User entered '1'	Lauren Evans (b) (4)	02 Nov 2020 14:53:23

FDA-CBER-2022-1614-3172283

US3752173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:45:09
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:44:40
User entered '0'	Lauren Evans (b) (4)	02 Nov 2020 14:53:23

FDA-CBER-2022-1614-3172284

US3752173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:45:09
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:44:42
User entered '0'	Lauren Evans (b) (4)	02 Nov 2020 14:53:23

US3752173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:45:09
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:44:44
User entered empty.	Lauren Evans (b) (4)	02 Nov 2020 14:53:23

US3752173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:45:09
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:44:47
User entered empty.	Lauren Evans (b) (4)	02 Nov 2020 14:53:23

US3752173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:45:09
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:44:49
User entered empty.	Lauren Evans (b) (4)	02 Nov 2020 14:53:23

FDA-CBER-2022-1614-3172288

US3752173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:45:09
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:44:51
User entered empty.	Lauren Evans (b) (4)	02 Nov 2020 14:53:23

FDA-CBER-2022-1614-3172289

US3752173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:45:09
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:44:52
User entered '0'	Lauren Evans (b) (4)	02 Nov 2020 14:53:23

US3752173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:45:09
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:44:58
User entered '0'	Lauren Evans (b) (4)	02 Nov 2020 14:53:23

FDA-CBER-2022-1614-3172291

US3752173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:45:09
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:45:01
User entered '0'	Lauren Evans (b) (4)	02 Nov 2020 14:53:23

US3752173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:45:09
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:45:03
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Nov 2020 15:14:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Nov 2020 15:14:37
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Lauren Evans (b) (4)	02 Nov 2020 15:14:37
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Nov 2020 14:53:23
User entered empty.	Lauren Evans (b) (4)	02 Nov 2020 14:53:23

US3752173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:45:09
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:45:05
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Nov 2020 15:14:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Nov 2020 15:14:37
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Lauren Evans (b) (4)	02 Nov 2020 15:14:37
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Nov 2020 14:53:23
User entered empty.	Lauren Evans (b) (4)	02 Nov 2020 14:53:23

US3752173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:45:09
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:45:08
User entered 'Not Applicable (NOT APPLICABLE)'	Lauren Evans (b) (4)	02 Nov 2020 14:53:23

US3752173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:45:09
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User closed query 'Per DM CLR: Please note that there is no Con Med/Con Proc listed for treatment of this condition and treatment would be expected. Diagnostic procedures are not considered treatment. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Jan 2021 15:05:24
Query 'Per DM CLR: Please note that there is no Con Med/Con Proc listed for treatment of this condition and treatment would be expected. Diagnostic procedures are not considered treatment. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment. ' answered with 'THERE IS NO TREATMENT BECAUSE SUBJECT PASSED AWAY.' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 15:49:18
User opened query 'Per DM CLR: Please note that there is no Con Med/Con Proc listed for treatment of this condition and treatment would be expected. Diagnostic procedures are not considered treatment. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment. ' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 05:03:50
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:45:12
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	02 Nov 2020 16:56:47
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Nov 2020 16:56:47
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	02 Nov 2020 14:53:23
User entered '0'	Lauren Evans (b) (4)	02 Nov 2020 14:53:23

US3752173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:45:09
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:45:14
User entered '0'	Lauren Evans (b) (4)	02 Nov 2020 14:53:23

US3752173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:45:09
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:45:16
User entered '0'	Lauren Evans (b) (4)	02 Nov 2020 14:53:23

US3752173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:45:09
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:45:17
User entered 'Fatal (FATAL)'	Lauren Evans (b) (4)	02 Nov 2020 14:53:23

US3752173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:45:09
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:45:19
User entered empty.	Lauren Evans (b) (4)	02 Nov 2020 14:53:23

US3752173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:45:09
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User closed query 'PV Query: Please provide the subject's medical circumstances prior to death.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 21:07:44
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 21:07:42
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 21:07:37
User closed query 'PV Query: Please provide autopsy results if performed. If not performed, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 21:07:35
Query 'PV Query: Please provide the subject's medical circumstances prior to death.' answered with 'Coronary artery disease, COPD, hypertension, hyperlipidemia, and a previous MI in 2015.' (Site from Safety).	Haylee Rowe (b) (4) (b) (4)	19 Nov 2020 22:02:36
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'No treatment was given for this event. The patient passed away peacefully at home. ' (Site from Safety).	Haylee Rowe (b) (4) (b) (4)	19 Nov 2020 22:01:05

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US3752173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:45:09
Narrative

Audit	User	Time (GMT)
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' answered with 'The patient had several comorbidities that associated to this Myocardial Infarction. According to patient's PCP and Cardiologist medical records, he has coronary artery disease, COPD, hypertension, hyperlipidemia, and a previous MI in 2015.' (Site from Safety).	Haylee Rowe (b) (4) (b) (4)	19 Nov 2020 22:00:34
Query 'PV Query: Please provide autopsy results if performed. If not performed, please state so.' answered with 'Wife was contacted on 19 NOV 2020 and stated that no autopsy was performed. ' (Site from Safety).	Haylee Rowe (b) (4) (b) (4)	19 Nov 2020 21:56:03
User closed query 'PV Query: Please provide/confirm the cause of death.' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 17:12:00
Query 'PV Query: Please provide/confirm the cause of death.' answered with 'Massive heart attack' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 17:06:22
User opened query 'PV Query: Please provide the subject's medical circumstances prior to death.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 23:11:26
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 23:11:15
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 23:11:01
User opened query 'PV Query: Please provide autopsy results if performed. If not performed, please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 23:10:30
User opened query 'PV Query: Please provide/confirm the cause of death.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 23:10:17
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:45:27

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US3752173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:45:09
Narrative

Audit	User	Time (GMT)
User entered 'Subject's daughter called the site on 02 NOV 2020 at 8:00 and to report that the subject had died of a "massive heart attack" on 01 NOV 2020'	Lauren Evans (b) (4)	02 Nov 2020 14:53:23

US3752173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:45:09
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User entered '1'	System	02 Nov 2020 14:53:23

US3752173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:45:09
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User entered '1'	System	02 Nov 2020 14:53:23

US3752173
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:45:09
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Generated On: 10 Jun 2021 09:45:09
Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:46:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 20:16:52

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:45:09
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:46:24
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: FISH OIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 10:08:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 10:08:07
Data point term sent to Coder	System	20 Aug 2020 20:18:49
User entered 'Fish oil'	(b) (4), (b) (6)	20 Aug 2020 20:17:51

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:45:09
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:46:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 20:17:51

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:45:09
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:46:33
User entered 'Prophylaxis for cardiac disease'	(b) (4), (b) (6)	20 Aug 2020 20:17:51

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:45:09
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:46:39
User entered '1200'	(b) (4), (b) (6)	20 Aug 2020 20:17:51

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:45:09
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:46:41
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Aug 2020 20:17:51

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:45:09
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:46:43
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:17:51

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:45:09
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:46:45
User entered 'once daily (QD)'	(b) (4), (b) (6)	20 Aug 2020 20:17:51

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:45:09
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:46:48
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:17:51

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:45:09
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:46:50
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Aug 2020 20:17:51

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:45:09
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:46:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:17:51

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:45:09
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:46:55
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:51:19
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 20:17:51
User entered 'un May 2005'	(b) (4), (b) (6)	20 Aug 2020 20:17:51

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:45:09
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:46:59
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 20:17:51

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:45:09
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:32:59
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 20:09:13
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 20:07:11
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 20:06:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 20:17:51

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:45:09
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:33:00
User entered '01 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 20:09:13
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	12 Nov 2020 20:07:11
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	12 Nov 2020 20:06:01
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:17:51

FDA-CBER-2022-1614-3172321

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:45:09
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:48:05
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:17:51

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:45:09
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User entered '1'	System	20 Aug 2020 20:17:51

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:45:09
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User entered '1'	System	20 Aug 2020 20:17:51

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:45:09
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User entered '804 (804)'	System	20 Aug 2020 20:17:51

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:45:09
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:49:00
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: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 20:19:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 20:19:21
Data point term sent to Coder	System	20 Aug 2020 20:18:50
User entered 'Omeprazole'	(b) (4), (b) (6)	20 Aug 2020 20:18:46

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:45:09
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:49:02
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:18:46

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:45:09
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:49:03
User entered 'GERD'	(b) (4), (b) (6)	20 Aug 2020 20:18:46

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:45:09
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:49:05
User entered '40'	(b) (4), (b) (6)	20 Aug 2020 20:18:46

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:45:09
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:49:08
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Aug 2020 20:18:46

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:45:09
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:49:10
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:18:46

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:45:09
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:49:13
User entered 'once daily (QD)'	(b) (4), (b) (6)	20 Aug 2020 20:18:46

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:45:09
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:49:15
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:18:46

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:45:09
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:49:17
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Aug 2020 20:18:46

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:45:09
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:49:20
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:18:46

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:45:09
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:49:24
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:51:19
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 20:18:46
User entered 'un Jan 2010'	(b) (4), (b) (6)	20 Aug 2020 20:18:46

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:45:09
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:49:28
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 20:18:46

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:45:09
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:33:12
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 20:06:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 20:18:46

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:45:09
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:33:13
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	12 Nov 2020 20:08:50
User entered '01 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 20:08:50
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	12 Nov 2020 20:06:13
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:18:46

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:45:09
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:49:31
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:18:46

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:45:09
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User entered '1'	System	20 Aug 2020 20:18:46

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US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:45:09
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User entered '1'	System	20 Aug 2020 20:18:46

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:45:09
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User entered '804 (804)'	System	20 Aug 2020 20:18:46

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:45:09
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:49:42
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Aug 2020 20:20:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Aug 2020 20:20:22
Data point term sent to Coder	System	20 Aug 2020 20:19:52
User entered 'Aspirin'	(b) (4), (b) (6)	20 Aug 2020 20:19:43

FDA-CBER-2022-1614-3172344

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:45:09
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:49:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 20:19:43

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:45:09
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:53:35
User entered 'Prophylaxis for cardiac disease'	(b) (4), (b) (6)	20 Aug 2020 20:19:43

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:45:09
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:53:43
User entered '81'	(b) (4), (b) (6)	20 Aug 2020 20:19:43

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:45:09
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:53:46
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Aug 2020 20:19:43

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:45:09
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:53:53
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:19:43

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:45:09
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:53:58
User entered 'once daily (QD)'	(b) (4), (b) (6)	20 Aug 2020 20:19:43

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:45:09
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:54:01
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:19:43

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:45:09
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:54:04
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Aug 2020 20:19:43

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:45:09
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:54:08
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:19:43

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:45:09
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:54:48
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:51:19
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 20:19:43
User entered 'un Jun 2015'	(b) (4), (b) (6)	20 Aug 2020 20:19:43

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:45:09
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:54:51
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 20:19:43

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:45:09
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:33:24
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 20:06:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 20:19:43

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:45:09
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:33:26
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	12 Nov 2020 20:08:00
User entered '01 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 20:08:00
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	12 Nov 2020 20:06:23
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:19:43

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:45:09
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:55:42
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:19:43

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:45:09
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User entered '1'	System	20 Aug 2020 20:19:43

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:45:09
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User entered '1'	System	20 Aug 2020 20:19:43

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:45:09
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User entered '804 (804)'	System	20 Aug 2020 20:19:43

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:45:09
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:55:59
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 20:22:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 20:22:26
Data point term sent to Coder	System	20 Aug 2020 20:20:59
User entered 'Carvedilol'	(b) (4), (b) (6)	20 Aug 2020 20:20:31

FDA-CBER-2022-1614-3172362

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:45:09
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:56:02
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:20:31

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:45:09
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:56:11
User entered 'Hypertension'	(b) (4), (b) (6)	20 Aug 2020 20:20:31

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:45:09
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:56:18
User entered '12.5'	(b) (4), (b) (6)	20 Aug 2020 20:20:31

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:45:09
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:56:21
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Aug 2020 20:20:31

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:45:09
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:56:27
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:20:31

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:45:09
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:56:31
User entered 'twice daily (BID)'	(b) (4), (b) (6)	20 Aug 2020 20:20:31

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:45:09
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:56:35
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:20:31

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:45:09
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:57:05
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Aug 2020 20:20:31

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:45:09
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:57:08
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:20:31

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:45:09
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:57:40
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:51:19
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 20:20:31
User entered 'un Jun 2015'	(b) (4), (b) (6)	20 Aug 2020 20:20:31

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:45:09
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:57:45
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 20:20:31

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:45:09
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:33:38
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 20:06:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 20:20:31

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:45:09
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:33:40
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	12 Nov 2020 20:07:44
User entered '01 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 20:07:44
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	12 Nov 2020 20:06:34
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:20:31

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:45:09
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:57:52
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:20:31

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:45:09
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User entered '2'	System	20 Aug 2020 20:20:31

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:45:09
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User entered '1'	System	20 Aug 2020 20:20:31

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:45:09
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User entered '804 (804)'	System	20 Aug 2020 20:20:31

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:45:09
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:58:24
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 20:22:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 20:22:26
Data point term sent to Coder	System	20 Aug 2020 20:22:00
User entered 'Atorvastatin'	(b) (4), (b) (6)	20 Aug 2020 20:21:13

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:45:09
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:58:33
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:21:13

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:45:09
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:58:39
User entered 'Hyperlipidemia'	(b) (4), (b) (6)	20 Aug 2020 20:21:13

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:45:09
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:58:44
User entered '5'	(b) (4), (b) (6)	20 Aug 2020 20:21:13

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:45:09
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:58:46
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Aug 2020 20:21:13

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:45:09
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:58:50
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:21:13

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US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:45:09
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:58:55
User entered 'once daily (QD)'	(b) (4), (b) (6)	20 Aug 2020 20:21:13

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:45:09
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:59:09
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:21:13

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:45:09
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:59:14
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Aug 2020 20:21:13

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:45:09
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:59:24
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:21:13

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:45:09
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:59:28
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:51:19
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 20:21:13
User entered 'un Jun 2015'	(b) (4), (b) (6)	20 Aug 2020 20:21:13

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:45:09
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:59:31
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 20:21:13

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:45:09
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:33:49
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 20:06:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 20:21:13

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:45:09
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:33:50
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	12 Nov 2020 20:07:24
User entered '01 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 20:07:24
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	12 Nov 2020 20:06:43
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:21:13

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US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:45:09
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:59:42
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:21:13

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:45:09
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User entered '1'	System	20 Aug 2020 20:21:13

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:45:09
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User entered '1'	System	20 Aug 2020 20:21:13

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:45:09
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User entered '804 (804)'	System	20 Aug 2020 20:21:13

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:45:09
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:00:47
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: BUDESONIDE;FORMOTEROL FUMARATE, PRODUCTSYNONYM: SYMBICORT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Oct 2020 16:27:14
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Oct 2020 16:27:14
Data point term sent to Coder	System	16 Oct 2020 16:21:26
Coding entries removed.	(b) (4), (b) (6)	16 Oct 2020 16:21:20
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: BUDESONIDE;FORMOTEROL FUMARATE, PRODUCTSYNONYM: SYMBICORT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 20:24:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 20:24:32
Data point term sent to Coder	System	20 Aug 2020 20:23:02
User entered 'Symbicort'	(b) (4), (b) (6)	20 Aug 2020 20:22:28

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:45:09
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:00:50
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:22:28

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:45:09
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:01:28
User entered 'Chronic obstructive pulmonary disease' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 16:21:20
User entered 'COPD'	(b) (4), (b) (6)	20 Aug 2020 20:22:28

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:45:09
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User closed query 'Per DM CLR: Please review the dose and unit recorded as this is not the standard dosage for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 16:18:17
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:02:39
Query 'Per DM CLR: Please review the dose and unit recorded as this is not the standard dosage for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'UPDATED' (Site from DM).	Amanda Horn (b) (4) (b) (4)	18 Nov 2020 16:02:12
DataPoint Un-verified.	Amanda Horn (b) (4) (b) (4)	18 Nov 2020 16:01:58
User entered '160/4.5' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	18 Nov 2020 16:01:58
User opened query 'Per DM CLR: Please review the dose and unit recorded as this is not the standard dosage for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 11:32:41
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:02:07
User entered '160/5'	(b) (4), (b) (6)	20 Aug 2020 20:22:28

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:45:09
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:02:10
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Aug 2020 20:22:28

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:45:09
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:02:44
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:22:28

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:45:09
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:03:05
User entered 'twice daily (BID)'	(b) (4), (b) (6)	20 Aug 2020 20:22:28

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:45:09
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:03:12
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:22:28

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:45:09
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:03:17
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4), (b) (6)	20 Aug 2020 20:22:28

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:45:09
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:03:48
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:22:28

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:45:09
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:03:51
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:51:19
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 20:22:28
User entered 'un Jun 2015'	(b) (4), (b) (6)	20 Aug 2020 20:22:28

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:45:09
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:03:59
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 20:22:28

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:45:09
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:33:59
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 20:10:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 20:22:28

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:45:09
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:34:01
User entered '01 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 20:10:44
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:22:28

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:45:09
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:04:12
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:22:28

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:45:09
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User entered '2'	System	20 Aug 2020 20:22:28

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:45:09
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User entered '1'	System	20 Aug 2020 20:22:28

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:45:09
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User entered '804 (804)'	System	20 Aug 2020 20:22:28

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:45:09
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:04:41
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOIDS, PRODUCT: FLUTICASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 16:57:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 16:57:00
Data point term sent to Coder	System	06 Oct 2020 15:39:47
Coding entries removed.	(b) (4), (b) (6)	06 Oct 2020 15:38:49
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOIDS, PRODUCT: FLUTICASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 06:31:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 06:31:17
Data point term sent to Coder	System	20 Aug 2020 20:24:07
User entered 'Fluticasone'	(b) (4), (b) (6)	20 Aug 2020 20:23:36

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:45:09
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:04:45
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:23:36

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:45:09
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:04:48
User entered 'Chronic obstructive pulmonary disease' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Oct 2020 15:38:49
User entered 'COPD'	(b) (4), (b) (6)	20 Aug 2020 20:23:36

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:45:09
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:05:14
User entered '50'	(b) (4), (b) (6)	20 Aug 2020 20:23:36

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:45:09
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 14:39:33
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Nov 2020 14:39:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:57:59
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Nov 2020 17:34:56
User entered 'mg (mg)' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	12 Nov 2020 16:48:51
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)	08 Oct 2020 19:40:34
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).	(b) (4), (b) (6)	06 Oct 2020 15:38:57
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Oct 2020 15:38:49
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)	06 Oct 2020 03:42:49
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Aug 2020 20:23:36

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:45:09
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User closed query 'Per CDM: Dose Unit is recorded as 'Other - MCG', however, please confirm if Unit can be selected from already available option ‘ug’. If so, please update as appropriate, else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 14:41:43
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:16:41
Query 'Per CDM: Dose Unit is recorded as 'Other - MCG', however, please confirm if Unit can be selected from already available option ‘ug’. If so, please update as appropriate, else clarify.' answered with 'corrected' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 14:39:42
DataPoint Un-verified.	(b) (4), (b) (6)	18 Nov 2020 14:39:33
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	18 Nov 2020 14:39:33
User opened query 'Per CDM: Dose Unit is recorded as 'Other - MCG', however, please confirm if Unit can be selected from already available option ‘ug’. If so, please update as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 09:45:08
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:58:01
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 17:34:56
User entered 'mcg' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Nov 2020 17:34:56
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:06:59
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:23:36

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:45:09
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:07:55
User entered 'once daily (QD)'	(b) (4), (b) (6)	20 Aug 2020 20:23:36

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:45:09
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:08:33
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:23:36

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:45:09
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:08:41
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4), (b) (6)	20 Aug 2020 20:23:36

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:45:09
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:08:43
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:23:36

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:45:09
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:09:07
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:51:19
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 20:23:36
User entered 'un Jun 2015'	(b) (4), (b) (6)	20 Aug 2020 20:23:36

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:45:09
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:09:10
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 20:23:36

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:45:09
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:34:11
User entered 'No (N)' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	12 Nov 2020 16:49:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 20:23:36

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:45:09
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:34:13
User entered '01 Nov 2020' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	12 Nov 2020 16:49:09
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:23:36

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:45:09
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:09:17
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:23:36

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:45:09
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User entered '1'	System	20 Aug 2020 20:23:36

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:45:09
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User entered '1'	System	20 Aug 2020 20:23:36

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:45:09
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User entered '804 (804)'	System	20 Aug 2020 20:23:36

FDA-CBER-2022-1614-3172433

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:45:09
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:09:41
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS INHIBITING URIC ACID PRODUCTION, PRODUCT: ALLOPURINOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 20:26:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 20:26:23
Data point term sent to Coder	System	20 Aug 2020 20:25:09
User entered 'Allopurinol'	(b) (4), (b) (6)	20 Aug 2020 20:24:25

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:45:09
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:09:44
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:24:25

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:45:09
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:09:47
User entered 'Gout'	(b) (4), (b) (6)	20 Aug 2020 20:24:25

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:45:09
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:10:04
User entered '300'	(b) (4), (b) (6)	20 Aug 2020 20:24:25

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:45:09
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:10:07
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Aug 2020 20:24:25

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:45:09
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:10:10
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:24:25

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:45:09
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:10:14
User entered 'once daily (QD)'	(b) (4), (b) (6)	20 Aug 2020 20:24:25

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:45:09
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:10:19
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:24:25

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:45:09
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:10:21
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Aug 2020 20:24:25

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:45:09
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:10:24
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:24:25

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:45:09
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:10:29
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:51:19
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 20:24:25
User entered 'un Jul 2018'	(b) (4), (b) (6)	20 Aug 2020 20:24:25

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:45:09
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:10:34
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 20:24:25

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:45:09
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:34:24
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 20:11:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 20:24:25

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:45:09
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:34:26
User entered '01 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 20:11:26
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:24:25

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:45:09
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:10:39
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:24:25

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:45:09
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User entered '1'	System	20 Aug 2020 20:24:25

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:45:09
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User entered '1'	System	20 Aug 2020 20:24:25

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:45:09
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User entered '804 (804)'	System	20 Aug 2020 20:24:25

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:45:09
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:11:39
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Aug 2020 20:27:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Aug 2020 20:27:26
Data point term sent to Coder	System	20 Aug 2020 20:26:20
User entered 'Tamsulosin'	(b) (4), (b) (6)	20 Aug 2020 20:25:55

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:45:09
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:11:41
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:25:55

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:45:09
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:11:57
User entered 'Enlarged prostate'	(b) (4), (b) (6)	20 Aug 2020 20:25:55

FDA-CBER-2022-1614-3172454

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:45:09
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:12:05
User entered '0.045'	(b) (4), (b) (6)	20 Aug 2020 20:25:55

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:45:09
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:12:14
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Aug 2020 20:25:55

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:45:09
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:12:19
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:25:55

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:45:09
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:12:21
User entered 'other (OTHER)'	(b) (4), (b) (6)	20 Aug 2020 20:25:55

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:45:09
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:12:29
User entered 'unknown'	(b) (4), (b) (6)	20 Aug 2020 20:25:55

FDA-CBER-2022-1614-3172459

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:45:09
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:12:45
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Aug 2020 20:25:55

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:45:09
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:12:49
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:25:55

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:45:09
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:12:59
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:51:19
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 20:25:55
User entered 'un Aug 2019'	(b) (4), (b) (6)	20 Aug 2020 20:25:55

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:45:09
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:13:02
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 20:25:55

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:45:09
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:34:36
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 20:12:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 20:25:55

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:45:09
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:34:38
User entered '01 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Nov 2020 20:12:09
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:25:55

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:45:09
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:13:07
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:25:55

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:45:09
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User entered empty.	System	20 Aug 2020 20:25:55

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:45:09
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User entered empty.	System	20 Aug 2020 20:25:55

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:45:09
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User entered empty.	System	20 Aug 2020 20:25:55

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:45:09
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:13:25
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Oct 2020 16:28:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Oct 2020 16:28:31
Data point term sent to Coder	System	16 Oct 2020 16:22:28
Coding entries removed.	(b) (4), (b) (6)	16 Oct 2020 16:21:46
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 20:28:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 20:28:28
Data point term sent to Coder	System	20 Aug 2020 20:27:22
User entered 'Albuterol'	(b) (4), (b) (6)	20 Aug 2020 20:26:48

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:45:09
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:13:28
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:26:48

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:45:09
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:13:30
User entered 'Chronic obstructive pulmonary disease' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 16:21:46
User entered 'COPD'	(b) (4), (b) (6)	20 Aug 2020 20:26:48

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:45:09
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User closed query 'Per DM CLR: Please remove extraneous details from the dose field and leave the numerical data only. Update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Jan 2021 18:58:11
Query 'Per DM CLR: Please remove extraneous details from the dose field and leave the numerical data only. Update as appropriate. ' answered with 'data changed per query' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	11 Jan 2021 22:31:35
DataPoint Un-verified.	Jamie Pettus (b) (4) (b) (4)	11 Jan 2021 22:31:21
User entered '3' reason for change: Per Query Resolution	Jamie Pettus (b) (4) (b) (4)	11 Jan 2021 22:31:21
User opened query 'Per DM CLR: Please remove extraneous details from the dose field and leave the numerical data only. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 07:38:16
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:40:11
User entered '0.5 mg/3 mg' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Nov 2020 20:38:06
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 18:59:06
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 18:59:04
User entered '3' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	12 Nov 2020 16:49:32
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 0.5mg/3mg). ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 19:40:42
User entered '2.5' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Oct 2020 18:12:58

US3752173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:45:09

Dose per administration

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 0.5mg/3mg). ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 18:10:46
User entered '2.5/3' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Oct 2020 18:10:38
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 0.5mg/3mg). ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 03:42:30
User entered '3'	(b) (4), (b) (6)	20 Aug 2020 20:26:48

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:45:09
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:14:00
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Oct 2020 18:12:58
User entered 'mL (mL)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Oct 2020 18:10:38
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Aug 2020 20:26:48

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:45:09
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:14:04
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:26:48

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:45:09
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:14:07
User entered 'once daily (QD)'	(b) (4), (b) (6)	20 Aug 2020 20:26:48

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:45:09
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:14:12
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:26:48

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:45:09
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:14:27
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 15:14:25
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:14:23
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4), (b) (6)	20 Aug 2020 20:26:48

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:45:09
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:14:30
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:26:48

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:45:09
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:14:36
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:51:19
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 20:26:48
User entered 'un Jan 2020'	(b) (4), (b) (6)	20 Aug 2020 20:26:48

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:45:09
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:15:02
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 20:26:48

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:45:09
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:35:10
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 20:12:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 20:26:48

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:45:09
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:35:12
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 20:12:38
User entered '01 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 20:12:38
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:15:19
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:26:48

FDA-CBER-2022-1614-3172484

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:45:09
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:15:22
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:26:48

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:45:09
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User entered '1'	System	20 Aug 2020 20:26:48

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:45:09
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User entered '1'	System	20 Aug 2020 20:26:48

FDA-CBER-2022-1614-3172487

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:45:09
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User entered '804 (804)'	System	20 Aug 2020 20:26:48

FDA-CBER-2022-1614-3172488

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:45:09
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:15:56
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN, PRODUCTSYNONYM: MUCINEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Oct 2020 16:28:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Oct 2020 16:28:30
Data point term sent to Coder	System	16 Oct 2020 16:22:29
Coding entries removed.	(b) (4), (b) (6)	16 Oct 2020 16:22:11
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN, PRODUCTSYNONYM: MUCINEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 20:29:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 20:29:29
Data point term sent to Coder	System	20 Aug 2020 20:28:25
User entered 'Mucinex'	(b) (4), (b) (6)	20 Aug 2020 20:27:25

FDA-CBER-2022-1614-3172489

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:45:09
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:16:00
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:27:25

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:45:09
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:16:03
User entered 'Chronic obstructive pulmonary disease' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 16:22:11
User entered 'COPD'	(b) (4), (b) (6)	20 Aug 2020 20:27:25

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:45:09
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:16:09
User entered '1200'	(b) (4), (b) (6)	20 Aug 2020 20:27:25

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:45:09
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:16:10
User entered 'mg (mg)'	(b) (4), (b) (6)	20 Aug 2020 20:27:25

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:45:09
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:16:12
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:27:25

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:45:09
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:16:15
User entered 'once daily (QD)'	(b) (4), (b) (6)	20 Aug 2020 20:27:25

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:45:09
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:16:19
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:27:25

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:45:09
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:16:18
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Aug 2020 20:27:25

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:45:09
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:16:23
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:27:25

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:45:09
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:16:25
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:51:19
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 20:27:25
User entered 'un Jan 2020'	(b) (4), (b) (6)	20 Aug 2020 20:27:25

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:45:09
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:16:28
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 20:27:25

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:45:09
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:35:22
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 20:13:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 20:27:25

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:45:09
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:35:24
User entered '01 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 20:13:02
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 15:16:38
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 15:16:34
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:27:25

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:45:09
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:16:40
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:27:25

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:45:09
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User entered '1'	System	20 Aug 2020 20:27:25

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:45:09
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User entered '1'	System	20 Aug 2020 20:27:25

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:45:09
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User entered '804 (804)'	System	20 Aug 2020 20:27:25

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:45:09
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:16:53
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 20:29:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 20:29:30
Data point term sent to Coder	System	20 Aug 2020 20:28:25
User entered 'Multivitamin'	(b) (4), (b) (6)	20 Aug 2020 20:28:04

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:45:09
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:16:58
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Oct 2020 15:40:28
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:28:04

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:45:09
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:17:14
User entered 'Supplement'	(b) (4), (b) (6)	20 Aug 2020 20:28:04

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:45:09
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:17:23
User entered '1'	(b) (4), (b) (6)	20 Aug 2020 20:28:04

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:45:09
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:17:27
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	20 Aug 2020 20:28:04

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:45:09
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:17:31
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:28:04

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:45:09
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:18:00
User entered 'once daily (QD)'	(b) (4), (b) (6)	20 Aug 2020 20:28:04

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:45:09
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:18:09
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:28:04

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:45:09
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:18:14
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Aug 2020 20:28:04

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:45:09
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:18:20
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:28:04

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:45:09
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:18:42
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:51:19
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 20:28:04
User entered 'un Feb 2019'	(b) (4), (b) (6)	20 Aug 2020 20:28:04

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:45:09
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:18:44
User entered '0'	(b) (4), (b) (6)	20 Aug 2020 20:28:04

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:45:09
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:35:37
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 20:13:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 20:28:04

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:45:09
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:35:39
User entered '01 Nov 2020' reason for change: New Information	(b) (4), (b) (6)	12 Nov 2020 20:13:58
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 20:28:04

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:45:09
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:18:57
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 20:28:04

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:45:09
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User entered '1'	System	20 Aug 2020 20:28:04

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:45:09
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User entered '1'	System	20 Aug 2020 20:28:04

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:45:09
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User entered '804 (804)'	System	20 Aug 2020 20:28:04

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:45:09
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:19:57
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 19:47:17
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 19:47:17
Data point term sent to Coder	System	26 Oct 2020 19:34:30
Coding entries removed.	(b) (4), (b) (6)	26 Oct 2020 19:34:17
Coding entries removed.	(b) (4), (b) (6)	26 Oct 2020 19:34:17
User entered 'Seasonal influenza vaccine' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 19:34:17
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Oct 2020 03:40:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Oct 2020 03:40:26
Data point term sent to Coder	System	23 Oct 2020 19:21:57
User entered 'Influenza Vaccination'	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 19:20:58

FDA-CBER-2022-1614-3172525

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:45:09
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:20:11
User entered 'Yes (Y)'	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 19:20:58

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:45:09
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:20:47
User entered 'Prophylaxis for seasonal influenza' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 19:34:17
User entered 'Seasonal Flu Prevention'	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 19:20:58

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:45:09
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:22:04
User entered '0.5' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 19:34:17
User entered '1'	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 19:20:58

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:45:09
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:22:06
User entered 'mL (mL)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 19:34:17
User entered 'Other (OTHER)'	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 19:20:58

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:45:09
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:22:07
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 19:34:17
User entered 'INJ'	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 19:20:58

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:45:09
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:22:10
User entered 'once (ONCE)'	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 19:20:58

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:45:09
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:22:11
User entered empty.	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 19:20:58

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:45:09
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:22:14
User entered 'Intramuscular (INTRAMUSCULAR)'	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 19:20:58

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:45:09
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:22:17
User entered empty.	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 19:20:58

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:45:09
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:22:20
User entered '20 Oct 2020'	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 19:20:58

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:45:09
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:22:23
User entered '0'	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 19:20:58

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:45:09
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:22:26
User entered 'No (N)'	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 19:20:58

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:45:09
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:22:33
User entered '20 Oct 2020'	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 19:20:58

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:45:09
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 15:22:39
User entered 'No (N)'	Haylee Rowe (b) (4) (b) (4)	23 Oct 2020 19:20:58

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:45:09
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User entered empty.	System	23 Oct 2020 19:20:58

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:45:09
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User entered empty.	System	23 Oct 2020 19:20:58

US3752173
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:45:09
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User entered empty.	System	23 Oct 2020 19:20:58

US3752173
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Generated On: 10 Jun 2021 09:45:09
Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:26:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:17:37
User entered 'No (N)'	(b) (4), (b) (6)	12 Nov 2020 19:56:52

US3752173
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 10 Jun 2021 09:45:09
Date of study discontinuation/completion *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:02:13
User entered '01 Nov 2020'	Haylee Rowe (b) (4) (b) (4)	12 Nov 2020 16:53:35

US3752173
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 10 Jun 2021 09:45:09
Reason for discontinuation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:27:04
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User closed query 'Death details are provided below, however Reason for Discontinuation is not Death. Please correct.' (Site from System).	System	23 Dec 2020 16:04:09
User entered 'Death (DEATH)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Dec 2020 16:04:09
User opened query 'Death details are provided below, however Reason for Discontinuation is not Death. Please correct.' (Site from System).	System	23 Dec 2020 16:03:50
DataPoint Un-verified.	(b) (4), (b) (6)	23 Dec 2020 16:03:50
User entered 'AE (specify) (ADVERSE EVENT)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Dec 2020 16:03:50
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:02:14
User entered 'Death (DEATH)'	Haylee Rowe (b) (4) (b) (4)	12 Nov 2020 16:53:35

US3752173
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 10 Jun 2021 09:45:09
If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:27:42
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User closed query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	23 Dec 2020 16:04:53
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	23 Dec 2020 16:04:53
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	23 Dec 2020 16:04:09
User closed query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	23 Dec 2020 16:03:50
User entered 'AE#1 MYOCARDIAL INFARCTION THAT RESULTED IN THE SUBJECT'S DEATH' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Dec 2020 16:03:50
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	23 Dec 2020 15:54:44
User entered 'AE#1 MYOCARDIAL INFARCTION' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Dec 2020 15:54:44
User closed query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	25 Nov 2020 14:59:41
User entered empty; reason for change Data Entry Error	Haylee Rowe (b) (4) (b) (4)	25 Nov 2020 14:59:41

US3752173
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 10 Jun 2021 09:45:09
If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	25 Nov 2020 14:59:17
User closed query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	25 Nov 2020 14:59:17
User entered 'SAE #1' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	25 Nov 2020 14:59:17
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	25 Nov 2020 14:58:54
DataPoint Un-verified.	Haylee Rowe (b) (4) (b) (4)	25 Nov 2020 14:58:54
User entered 'AE #1' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	25 Nov 2020 14:58:54
DataPoint Verified.	(b) (4), (b) (6)	25 Nov 2020 01:03:48
User closed query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	24 Nov 2020 14:25:31
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 14:25:31
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	24 Nov 2020 14:25:11
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 14:25:11
User entered 'AE #1' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 14:25:11
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:02:16

US3752173
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 10 Jun 2021 09:45:09
If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
User entered empty.	Haylee Rowe (b) (4) (b) (4)	12 Nov 2020 16:53:35

US3752173
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 10 Jun 2021 09:45:09
If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User closed query 'Main cause of death is not Other, however specify is provided. Please correct.' (Site from System).	System	23 Dec 2020 15:54:44
User opened query 'Main cause of death is not Other, however specify is provided. Please correct.' (Site from System).	System	23 Dec 2020 15:50:32
User closed query 'Per CDM Re-query: Kindly enter "AE#1" in the correct field not in the query response. Kindly update CRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 07:27:52
Query 'Per CDM Re-query: Kindly enter "AE#1" in the correct field not in the query response. Kindly update CRF as appropriate. ' answered with 'Please clarify what you're asking. If we enter AE #1 in the appropriate box it querys it. ' (Site from DM).	Haylee Rowe (b) (4) (b) (4)	25 Nov 2020 15:00:49
User closed query 'Per CDM: please consider adding record number (i.e. Adverse Event #1 or AE#1, etc.)' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 13:20:22
User opened query 'Per CDM Re-query: Kindly enter "AE#1" in the correct field not in the query response. Kindly update CRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 13:20:20
Query 'Per CDM: please consider adding record number (i.e. Adverse Event #1 or AE#1, etc.)' answered with 'AE#1' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 15:01:02
User opened query 'Per CDM: please consider adding record number (i.e. Adverse Event #1 or AE#1, etc.)' (Site from DM).	(b) (4), (b) (6)	21 Nov 2020 11:22:14
User closed query 'Per CDM: per sponsor review, please review source as there is an event recorded with outcome of Fatal and update accordingly ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 19:57:15
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:17:58
Query 'Per CDM: per sponsor review, please review source as there is an event recorded with outcome of Fatal and update accordingly ' answered with 'UPDATED' (Site from DM).	Amanda Horn (b) (4) (b) (4)	18 Nov 2020 16:09:41

US3752173
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 10 Jun 2021 09:45:09
If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
User closed query 'Main cause of death is not Other, however specify is provided. Please correct.' (Site from System).	System	18 Nov 2020 16:09:17
User opened query 'Main cause of death is not Other, however specify is provided. Please correct.' (Site from System).	System	18 Nov 2020 16:08:59
DataPoint Un-verified.	Amanda Horn (b) (4) (b) (4)	18 Nov 2020 16:08:59
User entered 'Adverse event (ADVERSE EVENT)' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	18 Nov 2020 16:08:59
User opened query 'Per CDM: per sponsor review, please review source as there is an event recorded with outcome of Fatal and update accordingly ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 11:37:27
Query 'Per CDM: per sponsor review, Death is recorded as Reason for Discontinuation, AE record number should be recorded. Please update accordingly' canceled (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 11:36:47
User opened query 'Per CDM: per sponsor review, Death is recorded as Reason for Discontinuation, AE record number should be recorded. Please update accordingly' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 09:59:43
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:02:19
User entered 'Other (OTHER)'	Haylee Rowe (b) (4) (b) (4)	12 Nov 2020 16:53:35

US3752173
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 10 Jun 2021 09:45:09
If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:27:34
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 18:41:02
User closed query 'Per CDM Re-query:Kindly consider adding record number (i.e. Adverse Event #1 or AE#1, etc.) ' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 01:47:40
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	23 Dec 2020 15:54:44
Query 'Per CDM Re-query:Kindly consider adding record number (i.e. Adverse Event #1 or AE#1, etc.) ' answered with 'CHANGED DATA PER QUERY' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 15:53:39
DataPoint Un-verified.	(b) (4), (b) (6)	23 Dec 2020 15:50:32
User entered 'AE#1' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Dec 2020 15:50:32
User opened query 'Per CDM Re-query:Kindly consider adding record number (i.e. Adverse Event #1 or AE#1, etc.) ' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 07:27:51
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:18:03
DataPoint Un-verified.	Amanda Horn (b) (4) (b) (4)	18 Nov 2020 16:09:17
User entered empty; reason for change Data Entry Error	Amanda Horn (b) (4) (b) (4)	18 Nov 2020 16:09:17
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:02:21
User entered 'MI'	Haylee Rowe (b) (4) (b) (4)	12 Nov 2020 16:53:35

US3752173
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 10 Jun 2021 09:45:09
Date of death *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:02:23
User entered '01 Nov 2020'	Haylee Rowe (b) (4) (b) (4)	12 Nov 2020 16:53:35

US3752173
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 10 Jun 2021 09:45:09
Was autopsy performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	20 Mar 2021 01:29:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 14:44:24
User closed query 'please verify as no per 19Nov progress note' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 14:44:21
Query 'please verify as no per 19Nov progress note' answered with 'updated' (Site from CRA).	Jamie Pettus (b) (4) (b) (4)	09 Mar 2021 20:36:55
Signature has been broken.	Jamie Pettus (b) (4) (b) (4)	09 Mar 2021 20:36:48
User entered 'No (N)' reason for change: Data Entry Error	Jamie Pettus (b) (4) (b) (4)	09 Mar 2021 20:36:48
User opened query 'please verify as no per 19Nov progress note' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 20:26:30
DataPoint Un-verified.	(b) (4), (b) (6)	08 Mar 2021 20:26:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 19:02:26
User entered 'Unknown (UNK)'	Haylee Rowe (b) (4) (b) (4)	12 Nov 2020 16:53:35

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US3752173
Folder: SAE USA-US113-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:09
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:41:25
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 13:09:05
User entered 'USA-US113-2020-MRNA-1273-P301000007'	System	03 Nov 2020 13:08:49

US3752173
Folder: SAE USA-US113-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:09
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:42:15
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 13:09:05
User entered 'Yes (Y)'	System	03 Nov 2020 13:08:49

US3752173
Folder: SAE USA-US113-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:09
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:42:17
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 13:09:05
User entered 'Yes (Y)'	System	03 Nov 2020 13:08:49

US3752173
Folder: SAE USA-US113-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:09
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:42:27
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 13:09:05
User entered 'No (N)'	System	03 Nov 2020 13:08:49

US3752173
Folder: SAE USA-US113-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:09
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:42:29
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 13:09:05
User entered 'No (N)'	System	03 Nov 2020 13:08:49

FDA-CBER-2022-1614-3172558

US3752173
Folder: SAE USA-US113-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:09
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:42:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 13:09:05
User entered 'No (N)'	System	03 Nov 2020 13:08:49

FDA-CBER-2022-1614-3172559

US3752173
Folder: SAE USA-US113-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:09
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:42:46
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 13:09:05
User entered 'No (N)'	System	03 Nov 2020 13:08:49

FDA-CBER-2022-1614-3172560

US3752173
Folder: SAE USA-US113-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:09
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:42:50
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 13:09:05
User entered 'No (N)'	System	03 Nov 2020 13:08:49

US3752173
Folder: SAE USA-US113-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:09
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:42:53
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 13:09:05
User entered 'Priyantha'	System	03 Nov 2020 13:08:49

US3752173
Folder: SAE USA-US113-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:09
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:42:55
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 13:09:05
User entered 'Wijewardane'	System	03 Nov 2020 13:08:49

FDA-CBER-2022-1614-3172563

US3752173
Folder: SAE USA-US113-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:09
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:42:59
User entered '9601 Baptist Health Drive,Suite 310'	Lauren Evans (b) (4)	04 Nov 2020 18:19:46

US3752173
Folder: SAE USA-US113-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:09
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:43:00
User entered 'Little Rock'	Lauren Evans (b) (4)	04 Nov 2020 18:19:46

US3752173
Folder: SAE USA-US113-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:09
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:43:02
User entered 'Arkansas'	Lauren Evans (b) (4)	04 Nov 2020 18:19:46

US3752173
Folder: SAE USA-US113-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:09
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:43:04
User entered '72022'	Lauren Evans (b) (4)	04 Nov 2020 18:19:46

FDA-CBER-2022-1614-3172567

US3752173
Folder: SAE USA-US113-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:09
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:43:07
User entered 'US'	System	03 Nov 2020 13:09:14

US3752173
Folder: SAE USA-US113-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:09
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '1'	(b) (4) System	03 Nov 2020 13:09:14

US3752173
Folder: SAE USA-US113-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:09
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:41:25
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 13:09:05
User entered 'USA-US113-2020-MRNA-1273-P301000007'	System	03 Nov 2020 13:08:49

FDA-CBER-2022-1614-3172570

US3752173
Folder: SAE USA-US113-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:09
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:42:15
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 13:09:05
User entered 'Yes (Y)'	System	03 Nov 2020 13:08:49

FDA-CBER-2022-1614-3172571

US3752173
Folder: SAE USA-US113-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:09
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:42:17
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 13:09:05
User entered 'Yes (Y)'	System	03 Nov 2020 13:08:49

US3752173
Folder: SAE USA-US113-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:09
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:42:27
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 13:09:05
User entered 'No (N)'	System	03 Nov 2020 13:08:49

US3752173
Folder: SAE USA-US113-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:09
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:42:29
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 13:09:05
User entered 'No (N)'	System	03 Nov 2020 13:08:49

FDA-CBER-2022-1614-3172574

US3752173
Folder: SAE USA-US113-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:09
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:42:36
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 13:09:05
User entered 'No (N)'	System	03 Nov 2020 13:08:49

FDA-CBER-2022-1614-3172575

US3752173
Folder: SAE USA-US113-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:09
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:42:46
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 13:09:05
User entered 'No (N)'	System	03 Nov 2020 13:08:49

FDA-CBER-2022-1614-3172576

US3752173
Folder: SAE USA-US113-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:09
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:42:50
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 13:09:05
User entered 'No (N)'	System	03 Nov 2020 13:08:49

FDA-CBER-2022-1614-3172577

US3752173
Folder: SAE USA-US113-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:09
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:42:53
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 13:09:05
User entered 'Priyantha'	System	03 Nov 2020 13:08:49

FDA-CBER-2022-1614-3172578

US3752173
Folder: SAE USA-US113-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:09
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:42:55
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 13:09:05
User entered 'Wijewardane'	System	03 Nov 2020 13:08:49

FDA-CBER-2022-1614-3172579

US3752173
Folder: SAE USA-US113-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:09
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:42:59
User entered '9601 Baptist Health Drive,Suite 310'	Lauren Evans (b) (4)	04 Nov 2020 18:19:46

FDA-CBER-2022-1614-3172580

US3752173
Folder: SAE USA-US113-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:09
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:43:00
User entered 'Little Rock'	Lauren Evans (b) (4)	04 Nov 2020 18:19:46

FDA-CBER-2022-1614-3172581

US3752173
Folder: SAE USA-US113-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:09
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:43:02
User entered 'Arkansas'	Lauren Evans (b) (4)	04 Nov 2020 18:19:46

FDA-CBER-2022-1614-3172582

US3752173
Folder: SAE USA-US113-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:09
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:43:04
User entered '72022'	Lauren Evans (b) (4)	04 Nov 2020 18:19:46

FDA-CBER-2022-1614-3172583

US3752173
Folder: SAE USA-US113-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:09
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:43:07
User entered 'US'	System	03 Nov 2020 13:09:14

US3752173
Folder: SAE USA-US113-2020-MRNA-1273-P301000007
Form: Safety Report Form
Generated On: 10 Jun 2021 09:45:09
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
User entered '1'	(b) (4) System	03 Nov 2020 13:09:14

US3752173
Folder: SAE USA-US113-2020-MRNA-1273-P301000007
Form: Safety Report Form (1)
Generated On: 10 Jun 2021 09:45:09
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 14:43:35
User entered '03/Nov/2020 08:09'	System	03 Nov 2020 13:09:14

FDA-CBER-2022-1614-3172586

US3752173

Folder: SAE USA-US113-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:45:09

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:27:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 18:41:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 14:43:39
User entered '1'	(b) (4), (b) (6)	03 Nov 2020 13:09:14