US3752259 (Prod: Baptist Health Center for Clinical Research)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:47:59

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US3752259
Form: Participant Creation
Data signed: (b) (4) **12 Feb 2021 19:15:08**
Generated On: 10 Jun 2021 09:47:59

Participant ID	US3752259

mRNA-1273-P301 Completion Guidelines

FDA-CBER-2022-1614-3180529

US3752259
Folder: Screening
Form: Visit Date
Data signed: (b) (4) **12 Feb 2021 19:15:10**
Generated On: 10 Jun 2021 09:47:59

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	26 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	SCRN

FDA-CBER-2022-1614-3180530

US3752259
Folder: Screening
Form: Demographics
Data signed: (b) (4) **12 Feb 2021 19:15:09**
Generated On: 10 Jun 2021 09:47:59

Date of Birth (MMM yyyy)	(b) (6) 1945
Age	74
Age Units	YEARS
Age (Derived)	74
Sex	Female ☐ Male ■
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ■ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify	
Unknown	False
Not reported	False

FDA-CBER-2022-1614-3180531

US3752259
Folder: Screening
Form: Enrollment
Data signed: (b) (4) **12 Feb 2021 19:15:09**
Generated On: 10 Jun 2021 09:47:59

Date of Informed Consent *(dd MMM yyyy)*	26 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-2022-1614-3180532

US3752259
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Data signed: (b) (4) **12 Feb 2021 19:15:09**
Generated On: 10 Jun 2021 09:47:59

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

US3752259
Folder: Screening
Form: Medical History Summary
Data signed: (b) (4) **12 Feb 2021 19:15:10**
Generated On: 10 Jun 2021 09:47:59

Were any significant conditions reported?	Yes ■ No ☐

FDA-CBER-2022-1614-3180534

US3752259
Folder: Screening
Form: Medical History (1)
Data signed: (b) (4) **12 Feb 2021 19:15:09**
Generated On: 10 Jun 2021 09:47:59

Condition	GLASSES (UNKNOWN ASSOCIATED CONDITION/DIAGNOSIS)
Start date (dd MMM yyyy)	UN UNK 1960
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 1960
Start Year (derived)	1960
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-3180535

US3752259
Folder: Screening
Form: Medical History (2)
Data signed: (b) (4) **12 Feb 2021 19:15:09**
Generated On: 10 Jun 2021 09:47:59

Condition	MACULAR DEGENERATION
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-2022-1614-3180536

US3752259
Folder: Screening
Form: Medical History (3)
Data signed: (b) (4) **12 Feb 2021 19:15:09**
Generated On: 10 Jun 2021 09:47:59

Condition	HEARING LOSS
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-3180537

US3752259
Folder: Screening
Form: Medical History (4)
Data signed: (b) (4) **12 Feb 2021 19:15:09**
Generated On: 10 Jun 2021 09:47:59

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-3180538

US3752259
Folder: Screening
Form: Medical History (5)
Data signed: (b) (4) **12 Feb 2021 19:15:09**
Generated On: 10 Jun 2021 09:47:59

Condition	MIXED HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-3180539

US3752259
Folder: Screening
Form: Medical History (6)
Data signed: (b) (4) **12 Feb 2021 19:15:09**
Generated On: 10 Jun 2021 09:47:59

Condition	PNEUMONIA
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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US3752259
Folder: Screening
Form: Medical History (7)
Data signed: (b) (4) **12 Feb 2021 19:15:09**
Generated On: 10 Jun 2021 09:47:59

Condition	PREDIABETIC
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-2022-1614-3180541

US3752259
Folder: Screening
Form: Medical History (8)
Data signed: (b) (4) **12 Feb 2021 19:15:09**
Generated On: 10 Jun 2021 09:47:59

Condition	ULCERATIVE COLITIS HISTORY
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 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2019
Stop Year (derived)	2019

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US3752259
Folder: Screening
Form: Medical History (9)
Data signed: (b) (4) **12 Feb 2021 19:15:09**
Generated On: 10 Jun 2021 09:47:59

Condition	VASECTOMY
Start date (dd MMM yyyy)	UN UNK 1976
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ■
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1976
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1976
Start Year (derived)	1976
Stop Month and Year (derived)	JAN 1976
Stop Year (derived)	1976

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US3752259
Folder: Screening
Form: Medical History (10)
Data signed: (b) (4) **12 Feb 2021 19:15:09**
Generated On: 10 Jun 2021 09:47:59

Condition	OSTEOARTHRITIS (UNKNOWN SITE)
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

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US3752259
Folder: Screening
Form: Medical History (11)
Data signed: (b) (4) **12 Feb 2021 19:15:09**
Generated On: 10 Jun 2021 09:47:59

Condition	ECZEMA
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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US3752259
Folder: Screening
Form: Medical History (12)
Data signed: (b) (4) **12 Feb 2021 19:15:09**
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Condition	KIDNEY STONES
Start date (dd MMM yyyy)	UN UNK 1980
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 1980
Start Year (derived)	1980
Stop Month and Year (derived)	
Stop Year (derived)	

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US3752259
Folder: Screening
Form: Medical History (13)
Data signed: (b) (4) **12 Feb 2021 19:15:09**
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Condition	TONSILLECTOMY
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)	

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US3752259
Folder: Screening
Form: Medical History (14)
Data signed: (b) (4) **12 Feb 2021 19:15:09**
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Condition	INGUINAL HERNIA SURGERY TIMES 3
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)	

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US3752259
Folder: Screening
Form: Medical History (15)
Data signed: (b) (4) **12 Feb 2021 19:15:09**
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Condition	LIPOMA REMOVAL RIGHT NECK
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)	

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US3752259
Folder: Screening
Form: Medical History (16)
Data signed: (b) (4) **12 Feb 2021 19:15:09**
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Condition	CORONARY ARTERY BYPASS GRAFT
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)	

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US3752259
Folder: Screening
Form: Medical History (17)
Data signed: (b) (4) **12 Feb 2021 19:15:09**
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Condition	AORTIC VALVE REPLACEMENT
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)	

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US3752259
Folder: Screening
Form: Medical History (18)
Data signed: (b) (4) **12 Feb 2021 19:15:09**
Generated On: 10 Jun 2021 09:47:59

Condition	ADENOIDECTOMY
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)	

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US3752259
Folder: Screening
Form: Medical History (19)
Data signed: (b) (4) **12 Feb 2021 19:15:09**
Generated On: 10 Jun 2021 09:47:59

Condition	CORONARY ARTERY DISEASE
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)	

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US3752259
Folder: Screening
Form: Medical History (20)
Data signed: (b) (4) **12 Feb 2021 19:15:09**
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Condition	CARDIAC MURMUR DUE TO CORONARY ARTERY BYPASS GRAFTING AND AORTIC VALVE REPLACEMENT
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes ■ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	
Stop Year (derived)	

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US3752259
Folder: Screening
Form: Medical History (21)
Data signed: (b) (4) **12 Feb 2021 19:15:09**
Generated On: 10 Jun 2021 09:47:59

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

FDA-CBER-2022-1614-3180555

US3752259
Folder: Screening
Form: Vital Signs
Data signed: (b) (4) **12 Feb 2021 19:15:10**
Generated On: 10 Jun 2021 09:47:59

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	26 AUG 2020
Time of assessment *(00:00-23:59)*	09:50 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 09:50
Height *(xxx.x)*	71 in
Weight *(xxx.x)*	190 lb
BMI *(xxx.x)*	26.55503 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-2022-1614-3180556

US3752259
Folder: Screening
Form: Physical Examination
Data signed: (b) (4) **12 Feb 2021 19:15:10**
Generated On: 10 Jun 2021 09:47:59

Was the physical examination performed?	Yes ☑ No ☐
Date of examination *(dd MMM yyyy)*	26 AUG 2020

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

FDA-CBER-2022-1614-3180557

US3752259
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **12 Feb 2021 19:15:10**
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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	

US3752259
Folder: Visit 1 Day 1
Form: Visit Date
Data signed: (b) (4) **12 Feb 2021 19:15:10**
Generated On: 10 Jun 2021 09:47:59

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	26 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT1

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US3752259
Folder: Visit 1 Day 1
Form: Randomization
Data signed: (b) (4) **12 Feb 2021 19:15:10**
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What was the date of randomization? *(dd MMM yyyy)*	26 AUG 2020
What was the participant's randomization number?	188335
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-2022-1614-3180561

US3752259
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Data signed: (b) (4) **12 Feb 2021 19:15:10**
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Height	ND - Not Done
Weight	ND - Not Done

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US3752259
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **12 Feb 2021 19:15:10**
Generated On: 10 Jun 2021 09:47:59

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)*	26 AUG 2020
Time of assessment *(00:00-23:59)*	09:50 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 09:50
Temperature *(xxx.x)*	97.8 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	62 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	22 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	62 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-3180563

US3752259
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **12 Feb 2021 19:15:10**
Generated On: 10 Jun 2021 09:47:59

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)*	26 AUG 2020
Time of assessment *(00:00-23:59)*	11:10 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 11:10
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)*	22 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	92 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-3180564

US3752259
Folder: Visit 1 Day 1
Form: Physical Examination
Data signed: (b) (4) **12 Feb 2021 19:15:10**
Generated On: 10 Jun 2021 09:47:59

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.

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US3752259
Folder: Visit 1 Day 1
Form: Exposure
Data signed: (b) (4) **12 Feb 2021 19:15:10**
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Was study treatment given?	Yes ■ No ☐
If No, reason not given	Participant declined due to Adverse Event ☐ Physician withheld dose due to Adverse Event ☐ Death ☐ Lost To Follow-Up ☐ Physician Decision ☐ Pregnancy ☐ Protocol Deviation ☐ Study Terminated by Sponsor ☐ Withdrawal of Consent by Participant ☐ Confirmed COVID-19 ☐ Other ☐
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? *(dd MMM yyyy)*	26 AUG 2020
What was the treatment time? *(00:00-23:59)*	10:40 (24 HR)
Treatment Date and Time (derived)	26 AUG 2020 10:40
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

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US3752259
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Data signed: (b) (4) **12 Feb 2021 19:15:10**
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Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	26 AUG 2020
Collection time *(00:00-23:59)*	10:00 (24 HR)
Collection date and time (derived)	26 AUG 2020 10:00

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US3752259
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **12 Feb 2021 19:15:10**
Generated On: 10 Jun 2021 09:47:59

Collection date *(dd MMM yyyy)*			26 AUG 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:58	26 AUG 2020 09:58
Nasopharyngeal Swab 2	No		

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US3752259
Folder: Visit 1 Day 1
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 19:15:10**
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Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

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US3752259
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:47:59

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	26 AUG 2020 11:01
PC Open Date & Time	26 AUG 2020 11:00
PC Close Date & Time	26 AUG 2020 13:30

FDA-CBER-2022-1614-3180570

US3752259
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:47:59

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**	97.7 °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 14:30
PC Open Date & Time	26 AUG 2020 14:25
PC Close Date & Time	27 AUG 2020 11:59

FDA-CBER-2022-1614-3180571

US3752259
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:47:59

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**	97.3 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	27 AUG 2020 12:09
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3752259
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:47:59

TIMEPOINT	DAY 3

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	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	28 AUG 2020 17:10
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

FDA-CBER-2022-1614-3180573

US3752259
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:47:59

TIMEPOINT	DAY 4

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.7 °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	29 AUG 2020 18:04
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

FDA-CBER-2022-1614-3180574

US3752259
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:47:59

TIMEPOINT	DAY 5

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.7 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	30 AUG 2020 18:22
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3752259
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:47:59

TIMEPOINT	DAY 6

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.3 °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	31 AUG 2020 18:04
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3752259
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:47:59

TIMEPOINT	DAY 7

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.4 °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	01 SEP 2020 18:04
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:47:59

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	26 AUG 2020 11:03
PC Open Date & Time	26 AUG 2020 11:00
PC Close Date & Time	26 AUG 2020 13:30

FDA-CBER-2022-1614-3180578

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:47:59

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	26 AUG 2020 14:30
PC Open Date & Time	26 AUG 2020 14:25
PC Close Date & Time	27 AUG 2020 11:59

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:47:59

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	27 AUG 2020 12:09
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

FDA-CBER-2022-1614-3180580

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:47:59

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	28 AUG 2020 17:11
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

FDA-CBER-2022-1614-3180581

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:47:59

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	29 AUG 2020 18:04
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

FDA-CBER-2022-1614-3180582

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:47:59

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	30 AUG 2020 18:22
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

FDA-CBER-2022-1614-3180583

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:47:59

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	31 AUG 2020 18:04
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

FDA-CBER-2022-1614-3180584

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:47:59

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	01 SEP 2020 18:05
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

FDA-CBER-2022-1614-3180585

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-2022-1614-3180586

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:47:59

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☑ Yes ☐
PC Time stamp	26 AUG 2020 11:05
PC Open Date & Time	26 AUG 2020 11:00
PC Close Date & Time	26 AUG 2020 13:30

FDA-CBER-2022-1614-3180587

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-2022-1614-3180588

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:47:59

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	26 AUG 2020 14:31
PC Open Date & Time	26 AUG 2020 14:25
PC Close Date & Time	27 AUG 2020 11:59

FDA-CBER-2022-1614-3180589

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:47:59

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-2022-1614-3180590

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:47:59

	Yes ☐
PC Time stamp	27 AUG 2020 12:10
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

FDA-CBER-2022-1614-3180591

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:47:59

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-2022-1614-3180592

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:47:59

	Yes ☐
PC Time stamp	28 AUG 2020 17:11
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

FDA-CBER-2022-1614-3180593

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:47:59

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

FDA-CBER-2022-1614-3180594

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:47:59

	Yes ☐
PC Time stamp	29 AUG 2020 18:04
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

FDA-CBER-2022-1614-3180595

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:47:59

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

FDA-CBER-2022-1614-3180596

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:47:59

	Yes ☐
PC Time stamp	30 AUG 2020 18:23
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

FDA-CBER-2022-1614-3180597

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:47:59

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-2022-1614-3180598

	Yes ☐
PC Time stamp	31 AUG 2020 18:05
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:47:59

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-2022-1614-3180600

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:47:59

	Yes ☐
PC Time stamp	01 SEP 2020 18:05
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

FDA-CBER-2022-1614-3180601

US3752259
Folder: Safety Call Day 8 (1)
Form: Safety Call
Data signed: (b) (4) **12 Feb 2021 19:15:09**
Generated On: 10 Jun 2021 09:47:59

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	2 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-2022-1614-3180602

US3752259
Folder: Safety Call Day 8 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 19:15:09**
Generated On: 10 Jun 2021 09:47:59

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

FDA-CBER-2022-1614-3180603

US3752259
Folder: Safety Call Day 15 (1)
Form: Safety Call
Data signed: (b) (4) **12 Feb 2021 19:15:09**
Generated On: 10 Jun 2021 09:47:59

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	9 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-2022-1614-3180604

US3752259
Folder: Safety Call Day 15 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 19:15:09**
Generated On: 10 Jun 2021 09:47:59

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

FDA-CBER-2022-1614-3180605

US3752259
Folder: Safety Call Day 22 (1)
Form: Safety Call
Data signed: (b) (4) **12 Feb 2021 19:15:09**
Generated On: 10 Jun 2021 09:47:59

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	16 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-2022-1614-3180606

US3752259
Folder: Safety Call Day 22 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 19:15:09**
Generated On: 10 Jun 2021 09:47:59

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

FDA-CBER-2022-1614-3180607

US3752259
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Data signed: (b) (4) **12 Feb 2021 19:15:10**
Generated On: 10 Jun 2021 09:47:59

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	23 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT2

FDA-CBER-2022-1614-3180608

US3752259
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **12 Feb 2021 19:15:10**
Generated On: 10 Jun 2021 09:47:59

Timepoint	Pre-Dose ■ Post-Dose ☐
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	23 SEP 2020
Time of assessment *(00:00-23:59)*	09:17 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 09:17
Temperature *(xxx.x)*	97.8 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)*	150 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	70 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-3180609

US3752259
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **12 Feb 2021 19:15:10**
Generated On: 10 Jun 2021 09:47:59

Timepoint	Pre-Dose ☐ Post-Dose ■
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	23 SEP 2020
Time of assessment *(00:00-23:59)*	10:25 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 10:25
Temperature *(xxx.x)*	98.8 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)*	72 mmHg
Diastolic Blood Pressure units	MMHG

US3752259
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Data signed: (b) (4) **12 Feb 2021 19:15:10**
Generated On: 10 Jun 2021 09:47:59

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

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

FDA-CBER-2022-1614-3180611

US3752259
Folder: Visit 2 Day 29 (1)
Form: Exposure
Data signed: (b) (4) **12 Feb 2021 19:15:10**
Generated On: 10 Jun 2021 09:47:59

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)*	23 SEP 2020
What was the treatment time? *(00:00-23:59)*	10:10 (24 HR)
Treatment Date and Time (derived)	23 SEP 2020 10:10
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-2022-1614-3180612

US3752259
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **12 Feb 2021 19:15:10**
Generated On: 10 Jun 2021 09:47:59

Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	23 SEP 2020
Collection time *(00:00-23:59)*	09:22 (24 HR)
Collection date and time (derived)	23 SEP 2020 09:22

US3752259
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **12 Feb 2021 19:15:10**
Generated On: 10 Jun 2021 09:47:59

Collection date *(dd MMM yyyy)*			23 SEP 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:19	23 SEP 2020 09:19
Nasopharyngeal Swab 2	No		

FDA-CBER-2022-1614-3180614

US3752259
Folder: Visit 2 Day 29 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 19:15:10**
Generated On: 10 Jun 2021 09:47:59

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

FDA-CBER-2022-1614-3180615

US3752259
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:47:59

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**	98.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	23 SEP 2020 10:31
PC Open Date & Time	23 SEP 2020 10:30
PC Close Date & Time	23 SEP 2020 13:00

FDA-CBER-2022-1614-3180616

US3752259
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:47:59

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**	96.7 °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	23 SEP 2020 18:06
PC Open Date & Time	23 SEP 2020 13:55
PC Close Date & Time	24 SEP 2020 11:59

US3752259
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:47:59

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**	99.1 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	24 SEP 2020 18:03
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3752259
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:47:59

TIMEPOINT	DAY 3

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.4 °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	25 SEP 2020 18:00
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3752259
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:47:59

TIMEPOINT	DAY 4

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	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	26 SEP 2020 18:01
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3752259
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:47:59

TIMEPOINT	DAY 5

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.9 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	27 SEP 2020 18:06
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3752259
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:47:59

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**	97.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	28 SEP 2020 18:10
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3752259
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:47:59

TIMEPOINT	DAY 7

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	97.3 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	29 SEP 2020 18:03
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:47:59

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	23 SEP 2020 10:31
PC Open Date & Time	23 SEP 2020 10:30
PC Close Date & Time	23 SEP 2020 13:00

FDA-CBER-2022-1614-3180624

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:47:59

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	23 SEP 2020 18:07
PC Open Date & Time	23 SEP 2020 13:55
PC Close Date & Time	24 SEP 2020 11:59

FDA-CBER-2022-1614-3180625

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:47:59

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	24 SEP 2020 18:03
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

FDA-CBER-2022-1614-3180626

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:47:59

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	25 SEP 2020 18:01
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

FDA-CBER-2022-1614-3180627

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:47:59

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	26 SEP 2020 18:02
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

FDA-CBER-2022-1614-3180628

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:47:59

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	27 SEP 2020 18:07
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

FDA-CBER-2022-1614-3180629

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:47:59

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	28 SEP 2020 18:10
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

FDA-CBER-2022-1614-3180630

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:47:59

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	29 SEP 2020 18:04
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

FDA-CBER-2022-1614-3180631

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:47:59

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

FDA-CBER-2022-1614-3180632

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:47:59

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	23 SEP 2020 10:32
PC Open Date & Time	23 SEP 2020 10:30
PC Close Date & Time	23 SEP 2020 13:00

FDA-CBER-2022-1614-3180633

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-2022-1614-3180634

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:47:59

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	23 SEP 2020 18:07
PC Open Date & Time	23 SEP 2020 13:55
PC Close Date & Time	24 SEP 2020 11:59

FDA-CBER-2022-1614-3180635

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:47:59

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-2022-1614-3180636

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:47:59

	Yes ☐
PC Time stamp	24 SEP 2020 18:03
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

FDA-CBER-2022-1614-3180637

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:47:59

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-2022-1614-3180638

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:47:59

	Yes ☐
PC Time stamp	25 SEP 2020 18:02
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

FDA-CBER-2022-1614-3180639

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:47:59

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

FDA-CBER-2022-1614-3180640

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:47:59

	Yes ☐
PC Time stamp	26 SEP 2020 18:02
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

FDA-CBER-2022-1614-3180641

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-2022-1614-3180642

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:47:59

	Yes ☐
PC Time stamp	27 SEP 2020 18:07
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:47:59

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-2022-1614-3180644

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:47:59

	Yes ☐
PC Time stamp	28 SEP 2020 18:11
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

FDA-CBER-2022-1614-3180645

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:47:59

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-2022-1614-3180646

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:47:59

	Yes ☐
PC Time stamp	29 SEP 2020 18:04
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

FDA-CBER-2022-1614-3180647

US3752259
Folder: Safety Call Day 36 (1)
Form: Safety Call
Data signed: (b) (4) **12 Feb 2021 19:15:09**
Generated On: 10 Jun 2021 09:47:59

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	30 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-2022-1614-3180648

US3752259
Folder: Safety Call Day 36 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 19:15:09**
Generated On: 10 Jun 2021 09:47:59

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

FDA-CBER-2022-1614-3180649

US3752259
Folder: Safety Call Day 43 (1)
Form: Safety Call
Data signed: (b) (4) **12 Feb 2021 19:15:09**
Generated On: 10 Jun 2021 09:47:59

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	7 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-2022-1614-3180650

US3752259
Folder: Safety Call Day 43 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 19:15:09**
Generated On: 10 Jun 2021 09:47:59

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

FDA-CBER-2022-1614-3180651

US3752259
Folder: Safety Call Day 50 (1)
Form: Safety Call
Data signed: (b) (4) **12 Feb 2021 19:15:09**
Generated On: 10 Jun 2021 09:47:59

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	14 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-2022-1614-3180652

US3752259
Folder: Safety Call Day 50 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 19:15:09**
Generated On: 10 Jun 2021 09:47:59

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

FDA-CBER-2022-1614-3180653

US3752259
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Data signed: (b) (4) **12 Feb 2021 19:15:10**
Generated On: 10 Jun 2021 09:47:59

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	28 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT3

FDA-CBER-2022-1614-3180654

US3752259
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Data signed: (b) (4) **12 Feb 2021 19:15:11**
Generated On: 10 Jun 2021 09:47:59

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	28 OCT 2020
Time of assessment *(00:00-23:59)*	10:10 (24 HR)
Vital Signs Date and Time (derived)	28 OCT 2020 10:10
Temperature *(xxx.x)*	97.5 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)*	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	88 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-3180655

US3752259
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Data signed: (b) (4) **12 Feb 2021 19:15:10**
Generated On: 10 Jun 2021 09:47:59

Was the physical examination performed?	Yes ☑ No ☐
Date of examination *(dd MMM yyyy)*	28 OCT 2020

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

FDA-CBER-2022-1614-3180656

US3752259
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **12 Feb 2021 19:15:10**
Generated On: 10 Jun 2021 09:47:59

Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	28 OCT 2020
Collection time *(00:00-23:59)*	10:15 (24 HR)
Collection date and time (derived)	28 OCT 2020 10:15

FDA-CBER-2022-1614-3180657

US3752259
Folder: Visit 3 Day 57 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 19:15:10**
Generated On: 10 Jun 2021 09:47:59

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

FDA-CBER-2022-1614-3180658

US3752259
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 OCT 2020 16:43:09
Patient Cloud Open Date & Time	26 OCT 2020 00:01
Patient Cloud Close Date & Time	30 OCT 2020 23:59

FDA-CBER-2022-1614-3180659

US3752259
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 NOV 2020 06:46:29
Patient Cloud Open Date & Time	02 NOV 2020 00:01
Patient Cloud Close Date & Time	06 NOV 2020 23:59

FDA-CBER-2022-1614-3180660

US3752259
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 NOV 2020 00:08:42
Patient Cloud Open Date & Time	09 NOV 2020 00:01
Patient Cloud Close Date & Time	13 NOV 2020 23:59

FDA-CBER-2022-1614-3180661

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 100.4°F/38°C)	
Chills	
Cough	
Shortness of breath	
Difficulty breathing	
Fatigue	
Muscle aches	
Body aches	
Headache	
New loss of taste	
New loss of smell	
Sore throat	
Congestion	
Runny nose	
Nausea	
Vomiting	
Diarrhea	
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

FDA-CBER-2022-1614-3180662

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59

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

FDA-CBER-2022-1614-3180663

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 NOV 2020 00:01:52
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

FDA-CBER-2022-1614-3180664

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 DEC 2020 00:02:21
Patient Cloud Open Date & Time	04 DEC 2020 00:01
Patient Cloud Close Date & Time	08 DEC 2020 23:59

FDA-CBER-2022-1614-3180665

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 DEC 2020 00:02:11
Patient Cloud Open Date & Time	11 DEC 2020 00:01
Patient Cloud Close Date & Time	15 DEC 2020 23:59

FDA-CBER-2022-1614-3180666

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 DEC 2020 00:13:55
Patient Cloud Open Date & Time	18 DEC 2020 00:01
Patient Cloud Close Date & Time	22 DEC 2020 23:59

FDA-CBER-2022-1614-3180667

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ■
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ■
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ■
Date and time of submission	25 DEC 2020 06:27:01
Patient Cloud Open Date & Time	25 DEC 2020 00:01
Patient Cloud Close Date & Time	29 DEC 2020 23:59

FDA-CBER-2022-1614-3180668

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 JAN 2021 12:03:53
Patient Cloud Open Date & Time	01 JAN 2021 00:01
Patient Cloud Close Date & Time	05 JAN 2021 23:59

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 JAN 2021 07:04:16
Patient Cloud Open Date & Time	08 JAN 2021 00:01
Patient Cloud Close Date & Time	12 JAN 2021 23:59

FDA-CBER-2022-1614-3180670

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 JAN 2021 00:02:04
Patient Cloud Open Date & Time	15 JAN 2021 00:01
Patient Cloud Close Date & Time	19 JAN 2021 23:59

FDA-CBER-2022-1614-3180671

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 JAN 2021 00:09:55
Patient Cloud Open Date & Time	22 JAN 2021 00:01
Patient Cloud Close Date & Time	26 JAN 2021 23:59

FDA-CBER-2022-1614-3180672

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 JAN 2021 07:05:58
Patient Cloud Open Date & Time	29 JAN 2021 00:01
Patient Cloud Close Date & Time	02 FEB 2021 23:59

FDA-CBER-2022-1614-3180673

US3752259
Folder: Cosmetic Injections and Dermal Fillers
Form: Cosmetic Injection_ Dermal Filler eDiary
Generated On: 10 Jun 2021 09:47:59

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

FDA-CBER-2022-1614-3180674

US3752259
Folder: Safety Call Day 85 (1)
Form: Safety Call
Data signed: (b) (4) **12 Feb 2021 19:15:09**
Generated On: 10 Jun 2021 09:47:59

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	18 NOV 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

FDA-CBER-2022-1614-3180675

US3752259
Folder: Safety Call Day 85 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 19:15:09**
Generated On: 10 Jun 2021 09:47:59

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

FDA-CBER-2022-1614-3180676

US3752259
Folder: Safety Call Day 119 (1)
Form: Safety Call
Data signed: (b) (4) **12 Feb 2021 19:15:09**
Generated On: 10 Jun 2021 09:47:59

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

FDA-CBER-2022-1614-3180677

US3752259
Folder: Safety Call Day 119 (1)
Form: Continuing
Data signed: (b) (4) **12 Feb 2021 19:15:09**
Generated On: 10 Jun 2021 09:47:59

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

FDA-CBER-2022-1614-3180678

US3752259
Folder: Safety Call Day 149 (1)
Form: Safety Call
Data signed: (b) (4) **16 Mar 2021 13:08:17**
Generated On: 10 Jun 2021 09:47:59

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	21 JAN 2021
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

FDA-CBER-2022-1614-3180679

US3752259
Folder: Safety Call Day 149 (1)
Form: Continuing
Data signed: (b) (4) **17 Mar 2021 20:27:57**
Generated On: 10 Jun 2021 09:47:59

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

FDA-CBER-2022-1614-3180680

US3752259
Folder: Covid-19 Assessment (1)
Form: COVID-19 Contact
Generated On: 10 Jun 2021 09:47:59

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 ☐

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Generate Next COVID-19 Assessment	Yes ☐ No ☐

US3752259
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Data signed: (b) (4) **12 Mar 2021 16:22:02**
Generated On: 10 Jun 2021 09:47:59

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	UNBLND_DECIDE

FDA-CBER-2022-1614-3180683

US3752259
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Data signed: (b) (4) **23 Apr 2021 14:52:04**
Generated On: 10 Jun 2021 09:47:59

Date of updated informed consent *(dd MMM yyyy)*	06 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes ■ No ☐
Under what version of the Protocol was the Participant unblinded?	Amendment 5 ☐ Amendment 6 or later ■
Date of unblinding *(dd MMM yyyy)*	03 FEB 2021
Participant randomization assignment	mRNA-1273 ☐ Placebo ■
Actual Dose 1	mRNA-1273 ☐ Placebo ■ Not Administered ☐
Actual Dose 2	mRNA-1273 ☐ Placebo ■ Not Administered ☐
Will participant receive mRNA-1273?	Yes ☐ No ■
Placebo Only Flag	1
Continuing with mRNA-1273	

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US3752259
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **31 Mar 2021 14:20:26**
Generated On: 10 Jun 2021 09:47:59

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

FDA-CBER-2022-1614-3180685

US3752259
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Data signed: (b) (4) **31 Mar 2021 14:20:25**
Generated On: 10 Jun 2021 09:47:59

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

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US3752259
Folder: Adverse Events
Form: Adverse Events Summary
Data signed: (b) (4) **12 Feb 2021 19:15:08**
Generated On: 10 Jun 2021 09:47:59

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

If Yes, enter details on the Adverse Events form.

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US3752259
Folder: Adverse Events
Form: Adverse Events (1)
Data signed: (b) (4) **06 Apr 2021 23:22:03**
Generated On: 10 Jun 2021 09:47:59

AEID	USA-US113-2020-MRNA-1273-P30 1000015
Adverse event	SIMULTANEOUS OCCURRENCE OF ATRIAL FLUTTER
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)*	20 DEC 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ■
If not Ongoing, end date *(dd MMM yyyy)*	21 DEC 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ■
Is the adverse event serious?	Yes ■ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date *(dd MMM yyyy)*	20 DEC 2020
Hospital Discharge Date *(dd MMM yyyy)*	21 DEC 2020
Admitted to ICU?	Yes ☐ No ■ Unknown ☐

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ■ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ■ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ■
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ■ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	PATIENT IS TAKING ELIQUIS AND AMIODARONE FOR THIS ADVERSE EVENT.
Narrative	ADMITTED 20DEC2020WITH NEW ONSET A.FLUTTER. S/P CARDIOVERSION 21DEC2020. D/C HOME ON 21DEC2020. ASYMPTOMATIC AT DOSING.
Serious Adverse Event Derived (CSA Programming Field Ony)	1

US3752259
Folder: Adverse Events
Form: Adverse Events (1)
Data signed: (b) (4) **06 Apr 2021 23:22:03**
Generated On: 10 Jun 2021 09:47:59

Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3752259
Folder: Adverse Events
Form: Adverse Events (2)
Data signed: (b) (4) **06 Apr 2021 23:22:03**
Generated On: 10 Jun 2021 09:47:59

AEID	USA-US113-2020-MRNA-1273-P30 1000015
Adverse event	SIMULTANEOUS OCCURRENCE OF ATRIAL FIBRILLATION
Was this a medically-attended AE?	Yes ■ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ■
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ■
Start date *(dd MMM yyyy)*	20 DEC 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ■
If not Ongoing, end date *(dd MMM yyyy)*	21 DEC 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ■
Is the adverse event serious?	Yes ■ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date *(dd MMM yyyy)*	20 DEC 2020
Hospital Discharge Date *(dd MMM yyyy)*	21 DEC 2020
Admitted to ICU?	Yes ☐ No ■ Unknown ☐

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ■ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ■ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ■
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ■ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	ADMITTED 20DEC2020WITH NEW ONSET A.FLUTTER. S/P CARDIOVERSION 21DEC2020. D/C HOME ON 21DEC2020. ASYMPTOMATIC AT DOSING.
Serious Adverse Event Derived (CSA Programming Field Ony)	1
Medically Attended AE Derived (CSA Programming Field Only)	1

Admitted to ICU Derived (CSA Programming Field Only)	0

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Data signed: (b) (4) **12 Feb 2021 19:15:09**
Generated On: 10 Jun 2021 09:47:59

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

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

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US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Data signed: (b) (4) **12 Mar 2021 16:22:02**
Generated On: 10 Jun 2021 09:47:59

Name of Medication	MELOXICAM
Prophylaxis	Yes ☐ No ■
Indication	OSTEOARTHRITIS (UPPER AND LOWER EXTREMITIES)
Dose per administration	15
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐

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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 UNK 2019
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Data signed: (b) (4) **12 Mar 2021 16:22:02**
Generated On: 10 Jun 2021 09:47:59

Name of Medication	METOPROLOL
Prophylaxis	Yes ☐ No ■
Indication	HYPERTENSION
Dose per administration	100
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

FDA-CBER-2022-1614-3180697

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2019
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	21 DEC 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 ■

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Data signed: (b) (4) **12 Mar 2021 16:22:02**
Generated On: 10 Jun 2021 09:47:59

Name of Medication	SIMVASTATIN
Prophylaxis	Yes ☐ No ■
Indication	HYPERCHOLESTEROLEMIA
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-2022-1614-3180699

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2019
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	21 DEC 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 ■

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Data signed: (b) (4) **12 Mar 2021 16:22:02**
Generated On: 10 Jun 2021 09:47:59

Name of Medication	MESALAMINE
Prophylaxis	Yes ☐ No ■
Indication	ULCERATIVE COLITIS
Dose per administration	1.2
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-2022-1614-3180701

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

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Data signed: (b) (4) **12 Mar 2021 16:22:02**
Generated On: 10 Jun 2021 09:47:59

Name of Medication	MULTIVITAMIN
Prophylaxis	Yes ■ No ☐
Indication	GENERAL HEALTH 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 ☐

FDA-CBER-2022-1614-3180703

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

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Data signed: (b) (4) **12 Mar 2021 16:22:02**
Generated On: 10 Jun 2021 09:47:59

Name of Medication	ASPIRIN
Prophylaxis	Yes ■ No ☐
Indication	HEART HEALTH
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 ☐ Intraocular ☐

FDA-CBER-2022-1614-3180705

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2010
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	21 DEC 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 ■

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Data signed: (b) (4) **12 Mar 2021 16:22:02**
Generated On: 10 Jun 2021 09:47:59

Name of Medication	MAGNESIUM
Prophylaxis	Yes ■ No ☐
Indication	HEART HEALTH
Dose per administration	250
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

FDA-CBER-2022-1614-3180707

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

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Data signed: (b) (4) **12 Mar 2021 16:22:02**
Generated On: 10 Jun 2021 09:47:59

Name of Medication	MILK THISTLE
Prophylaxis	Yes ■ No ☐
Indication	LIVER HEALTH
Dose per administration	240
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-2022-1614-3180709

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2010
Start date completely unknown	False
Ongoing?	Yes ■ No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Data signed: (b) (4) **12 Mar 2021 16:22:02**
Generated On: 10 Jun 2021 09:47:59

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

FDA-CBER-2022-1614-3180711

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

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Data signed: (b) (4) **12 Mar 2021 16:22:02**
Generated On: 10 Jun 2021 09:47:59

Name of Medication	PRESERVISION
Prophylaxis	Yes ☐ No ■
Indication	DRY EYES
Dose per administration	2
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ■
If dose unit is Other, specify	GTT
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-2022-1614-3180713

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

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Data signed: (b) (4) **12 Mar 2021 16:22:02**
Generated On: 10 Jun 2021 09:47:59

Name of Medication	TIZANIDINE
Prophylaxis	Yes ☐ No ■
Indication	MUSCLE RELAXANT FOR MUSCLE SPASMS
Dose per administration	2
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-2022-1614-3180715

	Intraocular ☐
	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2017
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	3
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Data signed: (b) (4) **12 Mar 2021 16:22:02**
Generated On: 10 Jun 2021 09:47:59

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-2022-1614-3180717

	Intraocular ☐
	Intramuscular ■
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	14 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	14 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 ☐

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Data signed: (b) (4) **12 Mar 2021 16:22:02**
Generated On: 10 Jun 2021 09:47:59

Name of Medication	AMIODARONE
Prophylaxis	Yes ☐ No ■
Indication	ATRIAL FLUTTER
Dose per administration	200
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

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

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Data signed: (b) (4) **12 Mar 2021 16:22:02**
Generated On: 10 Jun 2021 09:47:59

Name of Medication	APIXABAN
Prophylaxis	Yes ■ No ☐
Indication	STROKE/BLOOD CLOT PROPHYLAXIS
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 ☐

FDA-CBER-2022-1614-3180721

	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 DEC 2020
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Data signed: (b) (4) **12 Mar 2021 16:22:02**
Generated On: 10 Jun 2021 09:47:59

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

FDA-CBER-2022-1614-3180723

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

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Data signed: (b) (4) **12 Mar 2021 16:22:02**
Generated On: 10 Jun 2021 09:47:59

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

FDA-CBER-2022-1614-3180725

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

Name of Medication	PLANT STANOL ESTER
Prophylaxis	Yes ☐ No ■
Indication	HEART HEALTH
Dose per administration	2
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)*	14 MAY 2018
Start date completely unknown	False
Ongoing?	Yes ■ No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Data signed: (b) (4) **12 Mar 2021 16:22:02**
Generated On: 10 Jun 2021 09:47:59

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

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	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ■
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	20 DEC 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	21 DEC 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 ■

FDA-CBER-2022-1614-3180730

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Data signed: (b) (4) **12 Mar 2021 16:22:02**
Generated On: 10 Jun 2021 09:47:59

Name of Medication	DILTIAZEM IN NORMAL SALINE
Prophylaxis	Yes ☐ No ■
Indication	ATRIAL FLUTTER
Dose per administration	100
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐

FDA-CBER-2022-1614-3180731

	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 DEC 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	21 DEC 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 ■

FDA-CBER-2022-1614-3180732

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Data signed: (b) (4) **12 Mar 2021 16:22:02**
Generated On: 10 Jun 2021 09:47:59

Name of Medication	ENOXAPARIN
Prophylaxis	Yes ■ No ☐
Indication	BLOOD CLOT PREVENTION
Dose per administration	90
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-2022-1614-3180733

	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 DEC 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	21 DEC 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 ■

FDA-CBER-2022-1614-3180734

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Data signed: (b) (4) **12 Mar 2021 16:22:02**
Generated On: 10 Jun 2021 09:47:59

Name of Medication	HEPARIN
Prophylaxis	Yes ■ No ☐
Indication	BLOOD CLOT PREVENTION
Dose per administration	25000
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-2022-1614-3180735

	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 DEC 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	21 DEC 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	METOPROLOL SUCCINATE
Prophylaxis	Yes ☐ No ■
Indication	ESSENTIAL HYPERTENSION
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)*	22 DEC 2020
Start date completely unknown	False
Ongoing?	Yes ■ No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ■ No ☐
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Data signed: (b) (4) **12 Mar 2021 16:22:02**
Generated On: 10 Jun 2021 09:47:59

Name of Medication	ELIQUIS
Prophylaxis	Yes ■ No ☐
Indication	ATRIAL FLUTTER
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-2022-1614-3180739

	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 JAN 2021
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

FDA-CBER-2022-1614-3180740

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Data signed: (b) (4) **12 Mar 2021 16:22:02**
Generated On: 10 Jun 2021 09:47:59

Name of Medication	PFIZER COVID VACCINE
Prophylaxis	Yes ■ No ☐
Indication	COVID PREVENTION
Dose per administration	0.3
Dose unit	mg ☐ ug ☐ mL ■ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ■ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

FDA-CBER-2022-1614-3180741

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

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Data signed: (b) (4) **12 Mar 2021 16:22:02**
Generated On: 10 Jun 2021 09:47:59

Name of Medication	PFIZER COVID VACCINE
Prophylaxis	Yes ■ No ☐
Indication	COVID PREVENTATIVE
Dose per administration	0.3
Dose unit	mg ☐ ug ☐ mL ■ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ■ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

FDA-CBER-2022-1614-3180743

	Intramuscular ■
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	02 FEB 2021
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	02 FEB 2021
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

US3752259
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Data signed: (b) (4) **12 Feb 2021 19:15:09**
Generated On: 10 Jun 2021 09:47:59

Were any concomitant procedures performed?	Yes ■ No ☐

If yes, please complete Concomitant Procedures form.

FDA-CBER-2022-1614-3180745

US3752259
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures
Data signed: (b) (4) **12 Feb 2021 19:15:09**
Generated On: 10 Jun 2021 09:47:59

Procedure/Surgery date *(dd MMM yyyy)*	Procedure/Surgery	Indication	If indication is Other, specify
20 DEC 2020	ECHO TTE	Adverse Event	
21 DEC 2020	EP-CARDIOVERSION WITH TRANSESOPHAGEAL ECHO	Adverse Event	

FDA-CBER-2022-1614-3180746

US3752259
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Data signed: (b) (4) **08 Apr 2021 13:41:31**
Generated On: 10 Jun 2021 09:47:59

Date of study discontinuation/completion *(dd MMM yyyy)*	03 FEB 2021
Reason for discontinuation	AE (specify) ☐ SAE (specify) ☐ Complete ☐ Death ☐ Lost To Follow-up ☐ Physician decision (specify) ☐ Pregnancy ☐ Protocol deviation (specify) ■ Study Terminated By Sponsor ☐ Withdrawal of consent by participant (specify) ☐ Other ☐
If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify	PATIENT RECEIVED THE PFIZER COVID VACCINE OUTSIDE OF THE STUDY SO IS THEREFORE BEING WITHDRAWN
If reason for discontinuation is Death, main cause of death	Adverse event ☐ Unknown ☐ Other ☐
If main cause of death is Other, specify	
Date of death *(dd MMM yyyy)*	
Was autopsy performed?	Yes ☐ No ☐ Unknown ☐

FDA-CBER-2022-1614-3180747

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Data signed: (b) (4) **13 Apr 2021 01:07:27**
Generated On: 10 Jun 2021 09:47:59

SAEID	USA-US113-2020-MRNA-1273-P301000015
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, MEDICAL TOWER1, STE 800
Site Address: City	LITTLE ROCK
Site Address: State	ARKANSAS
Site Address: Postal Code	72205
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8

FDA-CBER-2022-1614-3180748

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form (1)
Data signed: (b) (4) **13 Apr 2021 01:07:27**
Generated On: 10 Jun 2021 09:47:59

SAEID	USA-US113-2020-MRNA-1273-P301000015
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, MEDICAL TOWER1, STE 800
Site Address: City	LITTLE ROCK
Site Address: State	ARKANSAS
Site Address: Postal Code	72205
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	22/DEC/2020 14:53
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

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form (2)
Data signed: (b) (4) **13 Apr 2021 01:07:27**
Generated On: 10 Jun 2021 09:47:59

SAEID	USA-US113-2020-MRNA-1273-P301000015
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, MEDICAL TOWER1, STE 800
Site Address: City	LITTLE ROCK
Site Address: State	ARKANSAS
Site Address: Postal Code	72205
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	29/DEC/2020 09:59
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

FDA-CBER-2022-1614-3180750

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form (3)
Data signed: (b) (4) **13 Apr 2021 01:07:27**
Generated On: 10 Jun 2021 09:47:59

SAEID	USA-US113-2020-MRNA-1273-P301000015
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, MEDICAL TOWER1, STE 800
Site Address: City	LITTLE ROCK
Site Address: State	ARKANSAS
Site Address: Postal Code	72205
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	30/DEC/2020 14:39
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

FDA-CBER-2022-1614-3180751

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form (4)
Data signed: (b) (4) **13 Apr 2021 01:07:27**
Generated On: 10 Jun 2021 09:47:59

SAEID	USA-US113-2020-MRNA-1273-P301000015
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, MEDICAL TOWER1, STE 800
Site Address: City	LITTLE ROCK
Site Address: State	ARKANSAS
Site Address: Postal Code	72205
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	06/JAN/2021 15:05
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

FDA-CBER-2022-1614-3180752

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form (5)
Data signed: (b) (4) **13 Apr 2021 01:07:27**
Generated On: 10 Jun 2021 09:47:59

SAEID	USA-US113-2020-MRNA-1273-P301000015
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, MEDICAL TOWER1, STE 800
Site Address: City	LITTLE ROCK
Site Address: State	ARKANSAS
Site Address: Postal Code	72205
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	10/MAR/2021 11:23
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

FDA-CBER-2022-1614-3180753

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form (6)
Data signed: (b) (4) **13 Apr 2021 01:07:27**
Generated On: 10 Jun 2021 09:47:59

SAEID	USA-US113-2020-MRNA-1273-P301000015
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, MEDICAL TOWER1, STE 800
Site Address: City	LITTLE ROCK
Site Address: State	ARKANSAS
Site Address: Postal Code	72205
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	17/MAR/2021 11:51
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

FDA-CBER-2022-1614-3180754

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form (7)
Data signed: (b) (4) **13 Apr 2021 01:07:27**
Generated On: 10 Jun 2021 09:47:59

SAEID	USA-US113-2020-MRNA-1273-P301000015
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, MEDICAL TOWER1, STE 800
Site Address: City	LITTLE ROCK
Site Address: State	ARKANSAS
Site Address: Postal Code	72205
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	29/MAR/2021 11:46
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

FDA-CBER-2022-1614-3180755

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form (8)
Data signed: (b) (4) **13 Apr 2021 01:07:27**
Generated On: 10 Jun 2021 09:47:59

SAEID	USA-US113-2020-MRNA-1273-P301000015
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, MEDICAL TOWER1, STE 800
Site Address: City	LITTLE ROCK
Site Address: State	ARKANSAS
Site Address: Postal Code	72205
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	07/APR/2021 10:43
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

FDA-CBER-2022-1614-3180756

Audit

US3752259 (Prod: Baptist Health Center for Clinical Research)

FDA-CBER-2022-1614-3180757

US3752259
Form: Participant Creation
Generated On: 10 Jun 2021 09:47:59
Participant ID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:38:46
User entered 'US3752259'	RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 14:50:38

FDA-CBER-2022-1614-3180758

US3752259
Form: Participant Creation
Generated On: 10 Jun 2021 09:47:59

mRNA-1273-P301 Completion Guidelines

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04

FDA-CBER-2022-1614-3180759

US3752259
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 09:47:59
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:25:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 15:43:59

FDA-CBER-2022-1614-3180760

US3752259
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 09:47:59
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:25:09
User entered '26 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 14:50:39

FDA-CBER-2022-1614-3180761

US3752259
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 09:47:59
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 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:25:09
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	26 Aug 2020 15:43:59

FDA-CBER-2022-1614-3180762

US3752259
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 09:47:59
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered 'SCRN'	System	26 Aug 2020 15:43:59

US3752259
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:47:59
Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:38:56
User entered (b) (6) 1945'	RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 14:50:40

US3752259
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:47:59
Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:38:56
User entered '74'	(b) (4), (b) (6)	27 Aug 2020 15:06:39

US3752259
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:47:59
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered 'YEARS'	System	27 Aug 2020 15:06:39

FDA-CBER-2022-1614-3180766

US3752259
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:47:59
Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '74'	System	26 Aug 2020 15:44:16

US3752259
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:47:59
Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:38:56
User entered 'Male (M)'	(b) (4), (b) (6)	27 Aug 2020 15:06:39

US3752259
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:47:59
Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:38:56
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	27 Aug 2020 15:06:39

US3752259
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:47:59
White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:38:56
User entered '1'	(b) (4), (b) (6)	27 Aug 2020 15:06:39

US3752259
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:47:59
Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:38:56
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 15:06:39

FDA-CBER-2022-1614-3180771

US3752259
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:47:59
Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:38:56
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 15:06:39

FDA-CBER-2022-1614-3180772

US3752259
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:47:59
American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:38:56
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 15:06:39

US3752259
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:47:59
Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:38:56
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 15:06:39

FDA-CBER-2022-1614-3180774

US3752259
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:47:59
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:38:56
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 15:06:39

FDA-CBER-2022-1614-3180775

US3752259
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:47:59
If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:38:56
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:06:39

FDA-CBER-2022-1614-3180776

US3752259
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:47:59
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:38:56
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 15:06:39

FDA-CBER-2022-1614-3180777

US3752259
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 09:47:59
Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:38:56
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 15:06:39

FDA-CBER-2022-1614-3180778

US3752259
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:47:59
Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:40:06
User entered '26 Aug 2020'	(b) (4), (b) (6)	26 Aug 2020 15:44:16

FDA-CBER-2022-1614-3180779

US3752259
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:47:59
Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered 'Aug 2020'	System	26 Aug 2020 15:44:16

US3752259
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:47:59
Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '2020'	System	26 Aug 2020 15:44:16

FDA-CBER-2022-1614-3180781

US3752259
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:47:59
Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:40:06
User entered 'Amendment 2 (2)'	(b) (4), (b) (6)	26 Aug 2020 15:44:16

FDA-CBER-2022-1614-3180782

US3752259
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:47:59
Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:40:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 15:44:16

FDA-CBER-2022-1614-3180783

US3752259
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:47:59
If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:40:06
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 15:44:16

FDA-CBER-2022-1614-3180784

US3752259
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:47:59
If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:40:06
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 15:44:16

FDA-CBER-2022-1614-3180785

US3752259
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:47:59
Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:40:06
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 15:44:16

US3752259
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:47:59
If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:40:06
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 14:50:39

FDA-CBER-2022-1614-3180787

US3752259
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 09:47:59
Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '1'	System	26 Aug 2020 15:44:23

FDA-CBER-2022-1614-3180788

US3752259
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Generated On: 10 Jun 2021 09:47:59
Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:29:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 15:44:23

FDA-CBER-2022-1614-3180789

US3752259
Folder: Screening
Form: Medical History Summary
Generated On: 10 Jun 2021 09:47:59
Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:41:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 15:07:00

FDA-CBER-2022-1614-3180790

US3752259
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:47:59
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:32:41
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Eye therapeutic procedures NEC, PT: Eyeglasses therapy, LLT: Eyeglasses therapy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 05:49:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 05:49:41
User closed query 'Per DM CLR: Please update MH term to reflect a medical condition/diagnosis as appropriate. Please reconcile with the Con Med eCRF as necessary. ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 01:31:22
Data point term sent to Coder	System	13 Oct 2020 15:31:46
Query 'Per DM CLR: Please update MH term to reflect a medical condition/diagnosis as appropriate. Please reconcile with the Con Med eCRF as necessary. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 15:31:46
Coding entries removed.	(b) (4), (b) (6)	13 Oct 2020 15:31:41
User entered 'GLASSES (unknown associated condition/diagnosis)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Oct 2020 15:31:41
User opened query 'Per DM CLR: Please update MH term to reflect a medical condition/diagnosis as appropriate. Please reconcile with the Con Med eCRF as necessary. ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 02:23:17
User coded data point as SOC: Social circumstances, HLGT: Lifestyle issues, HLT: Disability issues, PT: Corrective lens user, LLT: Eyeglasses wearer - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:23:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:23:43
Data point term sent to Coder	System	27 Aug 2020 15:07:53

US3752259
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:47:59
Condition

Audit	User	Time (GMT)
User entered 'Glasses'	(b) (4), (b) (6)	27 Aug 2020 15:07:29

FDA-CBER-2022-1614-3180792

US3752259
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:47:59
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered 'un UNK 1960'	(b) (4), (b) (6)	27 Aug 2020 15:07:29

FDA-CBER-2022-1614-3180793

US3752259
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:47:59
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 15:07:29

FDA-CBER-2022-1614-3180794

US3752259
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:47:59
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 15:07:29

FDA-CBER-2022-1614-3180795

US3752259
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:47:59
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:07:29

FDA-CBER-2022-1614-3180796

US3752259
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:47:59
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 15:07:29

FDA-CBER-2022-1614-3180797

US3752259
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:47:59
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered 'Jan 1960'	System	27 Aug 2020 15:07:29

FDA-CBER-2022-1614-3180798

US3752259
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:47:59
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '1960'	System	27 Aug 2020 15:07:29

FDA-CBER-2022-1614-3180799

US3752259
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:47:59
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	27 Aug 2020 15:07:29

US3752259
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 09:47:59
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	27 Aug 2020 15:07:29

FDA-CBER-2022-1614-3180801

US3752259
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:47:59
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:32:41
User coded data point as SOC: Eye disorders, HLGT: Ocular structural change, deposit and degeneration NEC, HLT: Retinal structural change, deposit and degeneration, PT: Macular degeneration, LLT: Macular degeneration - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:23:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:23:42
Data point term sent to Coder	System	27 Aug 2020 15:07:54
User entered 'Macular degeneration'	(b) (4), (b) (6)	27 Aug 2020 15:07:49

US3752259
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:47:59
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered 'un UNK 2015'	(b) (4), (b) (6)	27 Aug 2020 15:07:49

FDA-CBER-2022-1614-3180803

US3752259
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:47:59
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 15:07:49

FDA-CBER-2022-1614-3180804

US3752259
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:47:59
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 15:07:49

FDA-CBER-2022-1614-3180805

US3752259
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:47:59
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:07:49

FDA-CBER-2022-1614-3180806

US3752259
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:47:59
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 15:07:49

US3752259
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:47:59
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered 'Jan 2015'	System	27 Aug 2020 15:07:49

FDA-CBER-2022-1614-3180808

US3752259
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:47:59
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '2015'	System	27 Aug 2020 15:07:49

FDA-CBER-2022-1614-3180809

US3752259
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:47:59
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	27 Aug 2020 15:07:49

FDA-CBER-2022-1614-3180810

US3752259
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 09:47:59
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	27 Aug 2020 15:07:49

FDA-CBER-2022-1614-3180811

US3752259
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:47:59
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:32:41
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Hearing disorders, HLT: Hearing losses, PT: Deafness, LLT: Hearing loss - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:23:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:23:51
Data point term sent to Coder	System	27 Aug 2020 15:08:57
User entered 'Hearing loss'	(b) (4), (b) (6)	27 Aug 2020 15:08:03

US3752259
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:47:59
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered 'un UNK 2010'	(b) (4), (b) (6)	27 Aug 2020 15:08:03

FDA-CBER-2022-1614-3180813

US3752259
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:47:59
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 15:08:03

FDA-CBER-2022-1614-3180814

US3752259
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:47:59
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 15:08:03

FDA-CBER-2022-1614-3180815

US3752259
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:47:59
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:08:03

US3752259
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:47:59
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 15:08:03

US3752259
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:47:59
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered 'Jan 2010'	System	27 Aug 2020 15:08:03

FDA-CBER-2022-1614-3180818

US3752259
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:47:59
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '2010'	System	27 Aug 2020 15:08:03

FDA-CBER-2022-1614-3180819

US3752259
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:47:59
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	27 Aug 2020 15:08:03

US3752259
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 09:47:59
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	27 Aug 2020 15:08:03

FDA-CBER-2022-1614-3180821

US3752259
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:47:59
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:32:41
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)	27 Aug 2020 19:23:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:23:51
Data point term sent to Coder	System	27 Aug 2020 15:08:57
User entered 'Hypertension'	(b) (4), (b) (6)	27 Aug 2020 15:08:22

FDA-CBER-2022-1614-3180822

US3752259
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:47:59
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered 'un UNK 2010'	(b) (4), (b) (6)	27 Aug 2020 15:08:22

FDA-CBER-2022-1614-3180823

US3752259
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:47:59
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 15:08:22

FDA-CBER-2022-1614-3180824

US3752259
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:47:59
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 15:08:22

FDA-CBER-2022-1614-3180825

US3752259
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:47:59
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:08:22

FDA-CBER-2022-1614-3180826

US3752259
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:47:59
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 15:08:22

FDA-CBER-2022-1614-3180827

US3752259
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:47:59
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered 'Jan 2010'	System	27 Aug 2020 15:08:22

FDA-CBER-2022-1614-3180828

US3752259
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:47:59
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '2010'	System	27 Aug 2020 15:08:22

FDA-CBER-2022-1614-3180829

US3752259
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:47:59
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	27 Aug 2020 15:08:22

FDA-CBER-2022-1614-3180830

US3752259
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 09:47:59
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	27 Aug 2020 15:08:22

FDA-CBER-2022-1614-3180831

US3752259
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 09:47:59
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:18:57
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User coded data point as SOC: Congenital, familial and genetic disorders, HLGT: Metabolic and nutritional disorders congenital, HLT: Inborn errors of lipid metabolism, PT: Type V hyperlipidaemia, LLT: Mixed hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Dec 2020 19:00:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Dec 2020 19:00:51
Data point term sent to Coder	System	22 Dec 2020 18:59:56
DataPoint Un-verified.	Lauren Evans (b) (4)	22 Dec 2020 18:59:50
Coding entries removed.	Lauren Evans (b) (4)	22 Dec 2020 18:59:50
User entered 'Mixed hyperlipidemia' reason for change: Data Entry Error	Lauren Evans (b) (4)	22 Dec 2020 18:59:50
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
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)	27 Aug 2020 19:23:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:23:47
Data point term sent to Coder	System	27 Aug 2020 15:08:57
User entered 'Hypercholesterolemia'	(b) (4), (b) (6)	27 Aug 2020 15:08:40

FDA-CBER-2022-1614-3180832

US3752259
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 09:47:59
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered 'un UNK 2010'	(b) (4), (b) (6)	27 Aug 2020 15:08:40

FDA-CBER-2022-1614-3180833

US3752259
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 09:47:59
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 15:08:40

US3752259
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 09:47:59
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 15:08:40

FDA-CBER-2022-1614-3180835

US3752259
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 09:47:59
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:08:40

US3752259
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 09:47:59
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 15:08:40

US3752259
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 09:47:59
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered 'Jan 2010'	System	27 Aug 2020 15:08:40

FDA-CBER-2022-1614-3180838

US3752259
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 09:47:59
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '2010'	System	27 Aug 2020 15:08:40

FDA-CBER-2022-1614-3180839

US3752259
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 09:47:59
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	27 Aug 2020 15:08:40

US3752259
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 09:47:59
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	27 Aug 2020 15:08:40

FDA-CBER-2022-1614-3180841

US3752259
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 09:47:59
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:32:41
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Pneumonia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:24:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:24:23
Data point term sent to Coder	System	27 Aug 2020 15:09:58
User entered 'Pneumonia'	(b) (4), (b) (6)	27 Aug 2020 15:09:07

US3752259
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 09:47:59
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered 'un UNK 2015'	(b) (4), (b) (6)	27 Aug 2020 15:09:07

FDA-CBER-2022-1614-3180843

US3752259
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 09:47:59
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 15:09:07

FDA-CBER-2022-1614-3180844

US3752259
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 09:47:59
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 15:09:07

FDA-CBER-2022-1614-3180845

US3752259
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 09:47:59
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered 'un UNK 2015'	(b) (4), (b) (6)	27 Aug 2020 15:09:07

FDA-CBER-2022-1614-3180846

US3752259
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 09:47:59
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 15:09:07

FDA-CBER-2022-1614-3180847

US3752259
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 09:47:59
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered 'Jan 2015'	System	27 Aug 2020 15:09:07

FDA-CBER-2022-1614-3180848

US3752259
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 09:47:59
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '2015'	System	27 Aug 2020 15:09:07

FDA-CBER-2022-1614-3180849

US3752259
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 09:47:59
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered 'Jan 2015'	System	27 Aug 2020 15:09:07

FDA-CBER-2022-1614-3180850

US3752259
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 09:47:59
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '2015'	System	27 Aug 2020 15:09:07

FDA-CBER-2022-1614-3180851

US3752259
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:47:59
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:19:17
User closed query 'Please verify if this condition is accurate, as source indicates subject is "Pre-Diabetic".' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 17:10:31
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Hyperglycaemic conditions NEC, PT: Glucose tolerance impaired, LLT: Pre-diabetic - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 14:25:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 14:25:00
Data point term sent to Coder	System	23 Nov 2020 14:23:36
Query 'Please verify if this condition is accurate, as source indicates subject is "Pre-Diabetic".' answered with 'corrected' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 14:23:14
Coding entries removed.	(b) (4), (b) (6)	23 Nov 2020 14:23:07
User entered 'Prediabetic' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 14:23:07
User opened query 'Please verify if this condition is accurate, as source indicates subject is "Pre-Diabetic".' (Site from CRA).	(b) (4), (b) (6)	21 Nov 2020 16:10:06
DataPoint Un-verified.	(b) (4), (b) (6)	21 Nov 2020 16:08:48
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:05:31
DataPoint Un-verified.	(b) (4), (b) (6)	18 Nov 2020 16:34:20
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Hyperglycaemic conditions NEC, PT: Glucose tolerance impaired, LLT: Borderline diabetes - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:24:23

FDA-CBER-2022-1614-3180852

US3752259
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:47:59
Condition

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:24:23
Data point term sent to Coder	System	27 Aug 2020 15:10:01
User entered 'Borderline diabetes'	(b) (4), (b) (6)	27 Aug 2020 15:09:25

FDA-CBER-2022-1614-3180853

US3752259
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:47:59
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:40:43
DataPoint Un-verified.	(b) (4), (b) (6)	18 Nov 2020 16:34:20
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered 'un UNK 2019'	(b) (4), (b) (6)	27 Aug 2020 15:09:25

FDA-CBER-2022-1614-3180854

US3752259
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:47:59
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:40:45
DataPoint Un-verified.	(b) (4), (b) (6)	18 Nov 2020 16:34:20
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 15:09:25

FDA-CBER-2022-1614-3180855

US3752259
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:47:59
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:40:46
DataPoint Un-verified.	(b) (4), (b) (6)	18 Nov 2020 16:34:20
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 15:09:25

FDA-CBER-2022-1614-3180856

US3752259
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:47:59
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:40:48
DataPoint Un-verified.	(b) (4), (b) (6)	18 Nov 2020 16:34:20
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:09:25

US3752259
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:47:59
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:40:55
DataPoint Un-verified.	(b) (4), (b) (6)	18 Nov 2020 16:34:20
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 15:09:25

FDA-CBER-2022-1614-3180858

US3752259
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:47:59
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered 'Jan 2019'	System	27 Aug 2020 15:09:25

US3752259
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:47:59
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '2019'	System	27 Aug 2020 15:09:25

FDA-CBER-2022-1614-3180860

US3752259
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:47:59
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	27 Aug 2020 15:09:25

US3752259
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 09:47:59
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	27 Aug 2020 15:09:25

FDA-CBER-2022-1614-3180862

US3752259
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 09:47:59
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:32:41
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal inflammatory conditions, HLT: Colitis (excl infective), PT: Colitis ulcerative, LLT: Ulcerative colitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 09:52:34
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 09:52:34
Data point term sent to Coder	System	19 Oct 2020 14:26:42
Coding entries removed.	(b) (4), (b) (6)	19 Oct 2020 14:26:37
User entered 'ULCERATIVE COLITIS history' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 14:26:37
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal inflammatory conditions, HLT: Colitis (excl infective), PT: Colitis ulcerative, LLT: Ulcerative colitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:24:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:24:57
Data point term sent to Coder	System	27 Aug 2020 15:11:02
User entered 'Ulcerative colitis'	(b) (4), (b) (6)	27 Aug 2020 15:10:02

US3752259
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 09:47:59
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered 'un UNK 2015'	(b) (4), (b) (6)	27 Aug 2020 15:10:02

FDA-CBER-2022-1614-3180864

US3752259
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 09:47:59
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 15:10:02

US3752259
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 09:47:59
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 15:10:02

FDA-CBER-2022-1614-3180866

US3752259
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 09:47:59
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered 'un UNK 2019'	(b) (4), (b) (6)	27 Aug 2020 15:10:02

US3752259
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 09:47:59
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 15:10:02

US3752259
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 09:47:59
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered 'Jan 2015'	System	27 Aug 2020 15:10:02

US3752259
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 09:47:59
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '2015'	System	27 Aug 2020 15:10:02

FDA-CBER-2022-1614-3180870

US3752259
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 09:47:59
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered 'Jan 2019'	System	27 Aug 2020 15:10:02

US3752259
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 09:47:59
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '2019'	System	27 Aug 2020 15:10:02

FDA-CBER-2022-1614-3180872

US3752259
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 09:47:59
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:32:41
User coded data point as SOC: Surgical and medical procedures, HLGT: Male genital tract therapeutic procedures, HLT: Male genital tract therapeutic procedures NEC, PT: Vasectomy, LLT: Vasectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:24:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:24:57
Data point term sent to Coder	System	27 Aug 2020 15:11:02
User entered 'Vasectomy'	(b) (4), (b) (6)	27 Aug 2020 15:10:38

FDA-CBER-2022-1614-3180873

US3752259
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 09:47:59
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered 'un UNK 1976'	(b) (4), (b) (6)	27 Aug 2020 15:10:38

FDA-CBER-2022-1614-3180874

US3752259
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 09:47:59
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 15:10:38

US3752259
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 09:47:59
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 15:10:38

US3752259
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 09:47:59
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered 'un UNK 1976'	(b) (4), (b) (6)	27 Aug 2020 15:10:38

US3752259
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 09:47:59
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 15:10:38

US3752259
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 09:47:59
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered 'Jan 1976'	System	27 Aug 2020 15:10:38

US3752259
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 09:47:59
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '1976'	System	27 Aug 2020 15:10:38

FDA-CBER-2022-1614-3180880

US3752259
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 09:47:59
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered 'Jan 1976'	System	27 Aug 2020 15:10:38

US3752259
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 09:47:59
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '1976'	System	27 Aug 2020 15:10:38

FDA-CBER-2022-1614-3180882

US3752259
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 09:47:59
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis NOS - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 14:58:01
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:05:31
DataPoint Un-verified.	(b) (4), (b) (6)	18 Nov 2020 16:45:33
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
Data point term sent to Coder	System	13 Oct 2020 15:34:53
Coding entries removed.	(b) (4), (b) (6)	13 Oct 2020 15:34:43
User entered 'OSTEOARTHRITIS (unknown site)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Oct 2020 15:34:43
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:25:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:25:34
Data point term sent to Coder	System	27 Aug 2020 15:12:02
User entered 'Osteoarthritis'	(b) (4), (b) (6)	27 Aug 2020 15:11:05

US3752259
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 09:47:59
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered 'un UNK 1990'	(b) (4), (b) (6)	27 Aug 2020 15:11:05

FDA-CBER-2022-1614-3180884

US3752259
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 09:47:59
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 15:11:05

FDA-CBER-2022-1614-3180885

US3752259
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 09:47:59
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 15:11:05

FDA-CBER-2022-1614-3180886

US3752259
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 09:47:59
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:11:05

US3752259
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 09:47:59
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 15:11:05

FDA-CBER-2022-1614-3180888

US3752259
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 09:47:59
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered 'Jan 1990'	System	27 Aug 2020 15:11:05

FDA-CBER-2022-1614-3180889

US3752259
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 09:47:59
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '1990'	System	27 Aug 2020 15:11:05

FDA-CBER-2022-1614-3180890

US3752259
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 09:47:59
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	27 Aug 2020 15:11:05

US3752259
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 09:47:59
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	27 Aug 2020 15:11:05

FDA-CBER-2022-1614-3180892

US3752259
Folder: Screening
Form: Medical History (11)
Generated On: 10 Jun 2021 09:47:59
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:32:41
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Eczema, LLT: Eczema - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:25:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:25:34
Data point term sent to Coder	System	27 Aug 2020 15:12:03
User entered 'Eczema'	(b) (4), (b) (6)	27 Aug 2020 15:11:18

US3752259
Folder: Screening
Form: Medical History (11)
Generated On: 10 Jun 2021 09:47:59
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered 'un UNK 2010'	(b) (4), (b) (6)	27 Aug 2020 15:11:18

FDA-CBER-2022-1614-3180894

US3752259
Folder: Screening
Form: Medical History (11)
Generated On: 10 Jun 2021 09:47:59
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 15:11:18

FDA-CBER-2022-1614-3180895

US3752259
Folder: Screening
Form: Medical History (11)
Generated On: 10 Jun 2021 09:47:59
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 15:11:18

FDA-CBER-2022-1614-3180896

US3752259
Folder: Screening
Form: Medical History (11)
Generated On: 10 Jun 2021 09:47:59
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:11:18

US3752259
Folder: Screening
Form: Medical History (11)
Generated On: 10 Jun 2021 09:47:59
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 15:11:18

FDA-CBER-2022-1614-3180898

US3752259
Folder: Screening
Form: Medical History (11)
Generated On: 10 Jun 2021 09:47:59
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered 'Jan 2010'	System	27 Aug 2020 15:11:18

US3752259
Folder: Screening
Form: Medical History (11)
Generated On: 10 Jun 2021 09:47:59
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '2010'	System	27 Aug 2020 15:11:18

FDA-CBER-2022-1614-3180900

US3752259
Folder: Screening
Form: Medical History (11)
Generated On: 10 Jun 2021 09:47:59
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	27 Aug 2020 15:11:18

US3752259
Folder: Screening
Form: Medical History (11)
Generated On: 10 Jun 2021 09:47:59
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	27 Aug 2020 15:11:18

US3752259
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 09:47:59
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:32:41
User coded data point as SOC: Renal and urinary disorders, HLGT: Urolithiases, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Kidney stones - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:25:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:25:34
Data point term sent to Coder	System	27 Aug 2020 15:12:02
User entered 'Kidney stones'	(b) (4), (b) (6)	27 Aug 2020 15:11:41

US3752259
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 09:47:59
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered 'un UNK 1980'	(b) (4), (b) (6)	27 Aug 2020 15:11:41

FDA-CBER-2022-1614-3180904

US3752259
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 09:47:59
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 15:11:41

US3752259
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 09:47:59
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Oct 2020 15:33:41
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Oct 2020 15:33:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 15:11:41

FDA-CBER-2022-1614-3180906

US3752259
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 09:47:59
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	13 Oct 2020 15:33:41
User entered 'un UNK 2016' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Oct 2020 15:33:03
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:11:41

FDA-CBER-2022-1614-3180907

US3752259
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 09:47:59
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 15:11:41

FDA-CBER-2022-1614-3180908

US3752259
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 09:47:59
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered 'Jan 1980'	System	27 Aug 2020 15:11:41

FDA-CBER-2022-1614-3180909

US3752259
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 09:47:59
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '1980'	System	27 Aug 2020 15:11:41

FDA-CBER-2022-1614-3180910

US3752259
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 09:47:59
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	13 Oct 2020 15:33:41
User entered 'Jan 2016'	System	13 Oct 2020 15:33:03
User entered empty.	System	27 Aug 2020 15:11:41

US3752259
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 09:47:59
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	13 Oct 2020 15:33:41
User entered '2016'	System	13 Oct 2020 15:33:03
User entered empty.	System	27 Aug 2020 15:11:41

US3752259
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 09:47:59
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
User closed query 'Per CDM CR: Please review this medical diagnosis as it was noted two different procedures were recorded at the same entry. Please update this separately and ensure this medical procedures are recorded as appropriate with the corresponding start and stop date. ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 01:31:44
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Tonsillar therapeutic procedures, PT: Tonsillectomy, LLT: Tonsillectomy - version MedDRA\\23.0.	Coder Import (b) (4)	13 Oct 2020 15:35:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Oct 2020 15:35:17
Data point term sent to Coder	System	13 Oct 2020 15:34:52
Query 'Per CDM CR: Please review this medical diagnosis as it was noted two different procedures were recorded at the same entry. Please update this separately and ensure this medical procedures are recorded as appropriate with the corresponding start and stop date. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 15:34:04
Coding entries removed.	(b) (4), (b) (6)	13 Oct 2020 15:33:58
User entered 'TONSILLECTOMY' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Oct 2020 15:33:58
User opened query 'Per CDM CR: Please review this medical diagnosis as it was noted two different procedures were recorded at the same entry. Please update this separately and ensure this medical procedures are recorded as appropriate with the corresponding start and stop date. ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 02:24:29

US3752259
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 09:47:59
Condition

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Tonsillar therapeutic procedures, PT: Adenotonsillectomy, LLT: Tonsillectomy & Adenoidectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:25:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:25:37
Data point term sent to Coder	System	27 Aug 2020 15:13:04
User entered 'Tonsillectomy & adenoidectomy'	(b) (4), (b) (6)	27 Aug 2020 15:12:07

US3752259
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 09:47:59
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:12:07

US3752259
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 09:47:59
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered '1'	(b) (4), (b) (6)	27 Aug 2020 15:12:07

US3752259
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 09:47:59
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 15:12:07

US3752259
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 09:47:59
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:12:07

US3752259
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 09:47:59
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered '1'	(b) (4), (b) (6)	27 Aug 2020 15:12:07

US3752259
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 09:47:59
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	27 Aug 2020 15:12:07

FDA-CBER-2022-1614-3180920

US3752259
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 09:47:59
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	27 Aug 2020 15:12:07

US3752259
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 09:47:59
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	27 Aug 2020 15:12:07

US3752259
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 09:47:59
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	27 Aug 2020 15:12:07

FDA-CBER-2022-1614-3180923

US3752259
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 09:47:59
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:32:41
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Hernia repairs, PT: Inguinal hernia repair, LLT: Inguinal hernia repair - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 09:59:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 09:59:44
Data point term sent to Coder	System	27 Aug 2020 15:13:04
User entered 'Inguinal hernia surgery times 3'	(b) (4), (b) (6)	27 Aug 2020 15:12:29

FDA-CBER-2022-1614-3180924

US3752259
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 09:47:59
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:12:29

US3752259
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 09:47:59
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered '1'	(b) (4), (b) (6)	27 Aug 2020 15:12:29

US3752259
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 09:47:59
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 15:12:29

FDA-CBER-2022-1614-3180927

US3752259
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 09:47:59
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:12:29

US3752259
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 09:47:59
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered '1'	(b) (4), (b) (6)	27 Aug 2020 15:12:29

FDA-CBER-2022-1614-3180929

US3752259
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 09:47:59
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	27 Aug 2020 15:12:29

US3752259
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 09:47:59
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	27 Aug 2020 15:12:29

FDA-CBER-2022-1614-3180931

US3752259
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 09:47:59
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	27 Aug 2020 15:12:29

FDA-CBER-2022-1614-3180932

US3752259
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 09:47:59
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	27 Aug 2020 15:12:29

FDA-CBER-2022-1614-3180933

US3752259
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 09:47:59
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:32:41
User coded data point as SOC: Surgical and medical procedures, HLGT: Soft tissue therapeutic procedures, HLT: Soft tissue therapeutic procedures NEC, PT: Lipoma excision, LLT: Lipoma excision - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Sep 2020 11:11:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Sep 2020 11:11:40
Data point term sent to Coder	System	27 Aug 2020 15:13:04
User entered 'Lipoma removal right neck'	(b) (4), (b) (6)	27 Aug 2020 15:12:53

US3752259
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 09:47:59
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:12:53

US3752259
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 09:47:59
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered '1'	(b) (4), (b) (6)	27 Aug 2020 15:12:53

US3752259
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 09:47:59
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 15:12:53

FDA-CBER-2022-1614-3180937

US3752259
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 09:47:59
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:12:53

US3752259
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 09:47:59
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered '1'	(b) (4), (b) (6)	27 Aug 2020 15:12:53

US3752259
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 09:47:59
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	27 Aug 2020 15:12:53

US3752259
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 09:47:59
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	27 Aug 2020 15:12:53

FDA-CBER-2022-1614-3180941

US3752259
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 09:47:59
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	27 Aug 2020 15:12:53

US3752259
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 09:47:59
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	27 Aug 2020 15:12:53

FDA-CBER-2022-1614-3180943

US3752259
Folder: Screening
Form: Medical History (16)
Generated On: 10 Jun 2021 09:47:59
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:32:41
User coded data point as SOC: Surgical and medical procedures, HLGT: Vascular therapeutic procedures, HLT: Arterial therapeutic procedures (excl aortic), PT: Coronary artery bypass, LLT: Coronary artery bypass graft - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 17:16:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 17:16:45
Data point term sent to Coder	System	01 Sep 2020 17:15:21
User closed query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' (Site from System).	System	01 Sep 2020 17:14:50
Query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' answered with 'done' (Site from System).	(b) (4), (b) (6)	01 Sep 2020 17:14:50
User entered 'CORONARY ARTERY BYPASS GRAFT' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 17:14:36
User opened query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' (Site from System).	Coder Import (b) (4) (b) (4)	31 Aug 2020 14:30:28
Data point term sent to Coder	System	27 Aug 2020 15:14:05
User entered 'Coronary artery bypass graft times 3 with aortic valve replacement'	(b) (4), (b) (6)	27 Aug 2020 15:13:21

US3752259
Folder: Screening
Form: Medical History (16)
Generated On: 10 Jun 2021 09:47:59
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:13:21

US3752259
Folder: Screening
Form: Medical History (16)
Generated On: 10 Jun 2021 09:47:59
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered '1'	(b) (4), (b) (6)	27 Aug 2020 15:13:21

FDA-CBER-2022-1614-3180946

US3752259
Folder: Screening
Form: Medical History (16)
Generated On: 10 Jun 2021 09:47:59
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 15:13:21

US3752259
Folder: Screening
Form: Medical History (16)
Generated On: 10 Jun 2021 09:47:59
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:13:21

US3752259
Folder: Screening
Form: Medical History (16)
Generated On: 10 Jun 2021 09:47:59
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered '1'	(b) (4), (b) (6)	27 Aug 2020 15:13:21

US3752259
Folder: Screening
Form: Medical History (16)
Generated On: 10 Jun 2021 09:47:59
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	27 Aug 2020 15:13:21

US3752259
Folder: Screening
Form: Medical History (16)
Generated On: 10 Jun 2021 09:47:59
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	27 Aug 2020 15:13:21

FDA-CBER-2022-1614-3180951

US3752259
Folder: Screening
Form: Medical History (16)
Generated On: 10 Jun 2021 09:47:59
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	27 Aug 2020 15:13:21

US3752259
Folder: Screening
Form: Medical History (16)
Generated On: 10 Jun 2021 09:47:59
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	27 Aug 2020 15:13:21

FDA-CBER-2022-1614-3180953

US3752259
Folder: Screening
Form: Medical History (17)
Generated On: 10 Jun 2021 09:47:59
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:32:41
User coded data point as SOC: Surgical and medical procedures, HLGT: Cardiac therapeutic procedures, HLT: Cardiac valve therapeutic procedures, PT: Aortic valve replacement, LLT: Aortic valve replacement - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 17:17:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Sep 2020 17:17:52
Data point term sent to Coder	System	01 Sep 2020 17:16:23
User entered 'Aortic valve replacement'	(b) (4), (b) (6)	01 Sep 2020 17:15:49

US3752259
Folder: Screening
Form: Medical History (17)
Generated On: 10 Jun 2021 09:47:59
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	01 Sep 2020 17:16:03
User opened query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	01 Sep 2020 17:15:49
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 17:15:49

US3752259
Folder: Screening
Form: Medical History (17)
Generated On: 10 Jun 2021 09:47:59
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 17:16:03
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:15:49

US3752259
Folder: Screening
Form: Medical History (17)
Generated On: 10 Jun 2021 09:47:59
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 17:15:49

FDA-CBER-2022-1614-3180957

US3752259
Folder: Screening
Form: Medical History (17)
Generated On: 10 Jun 2021 09:47:59
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 17:15:49

US3752259
Folder: Screening
Form: Medical History (17)
Generated On: 10 Jun 2021 09:47:59
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered '1'	(b) (4), (b) (6)	01 Sep 2020 17:15:49

US3752259
Folder: Screening
Form: Medical History (17)
Generated On: 10 Jun 2021 09:47:59
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	01 Sep 2020 17:15:49

FDA-CBER-2022-1614-3180960

US3752259
Folder: Screening
Form: Medical History (17)
Generated On: 10 Jun 2021 09:47:59
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	01 Sep 2020 17:15:49

FDA-CBER-2022-1614-3180961

US3752259
Folder: Screening
Form: Medical History (17)
Generated On: 10 Jun 2021 09:47:59
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	01 Sep 2020 17:15:49

US3752259
Folder: Screening
Form: Medical History (17)
Generated On: 10 Jun 2021 09:47:59
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	01 Sep 2020 17:15:49

FDA-CBER-2022-1614-3180963

US3752259
Folder: Screening
Form: Medical History (18)
Generated On: 10 Jun 2021 09:47:59
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:32:41
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Tonsillar therapeutic procedures, PT: Adenoidectomy, LLT: Adenoidectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 15:35:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 15:35:14
Data point term sent to Coder	System	13 Oct 2020 15:34:52
User entered 'Adenoidectomy'	(b) (4), (b) (6)	13 Oct 2020 15:34:20

US3752259
Folder: Screening
Form: Medical History (18)
Generated On: 10 Jun 2021 09:47:59
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 15:34:20

FDA-CBER-2022-1614-3180965

US3752259
Folder: Screening
Form: Medical History (18)
Generated On: 10 Jun 2021 09:47:59
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered '1'	(b) (4), (b) (6)	13 Oct 2020 15:34:20

US3752259
Folder: Screening
Form: Medical History (18)
Generated On: 10 Jun 2021 09:47:59
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 15:34:20

FDA-CBER-2022-1614-3180967

US3752259
Folder: Screening
Form: Medical History (18)
Generated On: 10 Jun 2021 09:47:59
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 15:34:20

US3752259
Folder: Screening
Form: Medical History (18)
Generated On: 10 Jun 2021 09:47:59
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered '1'	(b) (4), (b) (6)	13 Oct 2020 15:34:20

US3752259
Folder: Screening
Form: Medical History (18)
Generated On: 10 Jun 2021 09:47:59
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	13 Oct 2020 15:34:20

FDA-CBER-2022-1614-3180970

US3752259
Folder: Screening
Form: Medical History (18)
Generated On: 10 Jun 2021 09:47:59
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	13 Oct 2020 15:34:20

FDA-CBER-2022-1614-3180971

US3752259
Folder: Screening
Form: Medical History (18)
Generated On: 10 Jun 2021 09:47:59
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	13 Oct 2020 15:34:20

US3752259
Folder: Screening
Form: Medical History (18)
Generated On: 10 Jun 2021 09:47:59
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	13 Oct 2020 15:34:20

FDA-CBER-2022-1614-3180973

US3752259
Folder: Screening
Form: Medical History (19)
Generated On: 10 Jun 2021 09:47:59
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:32:41
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)	13 Oct 2020 15:37:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 15:37:26
Data point term sent to Coder	System	13 Oct 2020 15:35:54
User entered 'Coronary artery disease'	(b) (4), (b) (6)	13 Oct 2020 15:35:38

US3752259
Folder: Screening
Form: Medical History (19)
Generated On: 10 Jun 2021 09:47:59
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 15:35:38

US3752259
Folder: Screening
Form: Medical History (19)
Generated On: 10 Jun 2021 09:47:59
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered '1'	(b) (4), (b) (6)	13 Oct 2020 15:35:38

US3752259
Folder: Screening
Form: Medical History (19)
Generated On: 10 Jun 2021 09:47:59
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 15:35:38

FDA-CBER-2022-1614-3180977

US3752259
Folder: Screening
Form: Medical History (19)
Generated On: 10 Jun 2021 09:47:59
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 15:35:38

US3752259
Folder: Screening
Form: Medical History (19)
Generated On: 10 Jun 2021 09:47:59
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 15:35:38

US3752259
Folder: Screening
Form: Medical History (19)
Generated On: 10 Jun 2021 09:47:59
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	13 Oct 2020 15:35:38

FDA-CBER-2022-1614-3180980

US3752259
Folder: Screening
Form: Medical History (19)
Generated On: 10 Jun 2021 09:47:59
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	13 Oct 2020 15:35:38

FDA-CBER-2022-1614-3180981

US3752259
Folder: Screening
Form: Medical History (19)
Generated On: 10 Jun 2021 09:47:59
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	13 Oct 2020 15:35:38

FDA-CBER-2022-1614-3180982

US3752259
Folder: Screening
Form: Medical History (19)
Generated On: 10 Jun 2021 09:47:59
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	13 Oct 2020 15:35:38

FDA-CBER-2022-1614-3180983

US3752259
Folder: Screening
Form: Medical History (20)
Generated On: 10 Jun 2021 09:47:59
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:20:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
User closed query 'Per MM, please review and update the term to reflect the final diagnosis ' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Dec 2020 10:31:38
User coded data point as SOC: Investigations, HLGT: Cardiac and vascular investigations (excl enzyme tests), HLT: Cardiac auscultatory investigations, PT: Cardiac murmur, LLT: Cardiac murmur - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Dec 2020 20:03:20
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Dec 2020 20:03:20
Data point term sent to Coder	System	30 Dec 2020 15:50:54
Query 'Per MM, please review and update the term to reflect the final diagnosis ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 15:50:51
DataPoint Un-verified.	(b) (4), (b) (6)	30 Dec 2020 15:50:45
Coding entries removed.	(b) (4), (b) (6)	30 Dec 2020 15:50:45
User entered 'Cardiac murmur due to coronary artery bypass grafting and aortic valve replacement' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Dec 2020 15:50:45
User opened query 'Per MM, please review and update the term to reflect the final diagnosis ' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 21:34:20
User closed query 'Per MM, please review and update the term to reflect the final diagnosis ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 22:25:03
User coded data point as SOC: Investigations, HLGT: Cardiac and vascular investigations (excl enzyme tests), HLT: Cardiac auscultatory investigations, PT: Cardiac murmur, LLT: Cardiac murmur - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 23:41:50
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 23:41:50
Query 'Per source murmur is "Grade 1". Please update accordingly.' canceled (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 20:15:37

US3752259
Folder: Screening
Form: Medical History (20)
Generated On: 10 Jun 2021 09:47:59
Condition

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:15:31
Data point term sent to Coder	System	19 Nov 2020 16:39:57
Coding entries removed.	(b) (4), (b) (6)	19 Nov 2020 16:39:41
User entered 'CARDIAC MURMUR /GRADE 1' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 16:39:41
User opened query 'Per source murmur is "Grade 1". Please update accordingly.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 18:53:05
DataPoint Un-verified.	(b) (4), (b) (6)	18 Nov 2020 18:52:14
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
Query 'Per MM, please review and update the term to reflect the final diagnosis ' answered with 'Final diagnosis unknown' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 16:57:42
User opened query 'Per MM, please review and update the term to reflect the final diagnosis ' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 16:39:01
User coded data point as SOC: Investigations, HLGT: Cardiac and vascular investigations (excl enzyme tests), HLT: Cardiac auscultatory investigations, PT: Cardiac murmur, LLT: Cardiac murmur - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Oct 2020 18:51:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Oct 2020 18:51:45
Data point term sent to Coder	System	29 Oct 2020 18:51:03
User entered 'Cardiac murmur'	(b) (4), (b) (6)	29 Oct 2020 18:50:24

FDA-CBER-2022-1614-3180985

US3752259
Folder: Screening
Form: Medical History (20)
Generated On: 10 Jun 2021 09:47:59
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Query 'Please verify start date, as note in Medical History indicates diagnosis in 2012.' canceled (Site from CRA).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:16:30
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:16:27
User entered 'UN UNK 2012' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 16:39:41
User opened query 'Please verify start date, as note in Medical History indicates diagnosis in 2012.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 18:53:52
DataPoint Un-verified.	(b) (4), (b) (6)	18 Nov 2020 18:52:20
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered 'un UNK 2011'	(b) (4), (b) (6)	29 Oct 2020 18:50:24

US3752259
Folder: Screening
Form: Medical History (20)
Generated On: 10 Jun 2021 09:47:59
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered '0'	(b) (4), (b) (6)	29 Oct 2020 18:50:24

US3752259
Folder: Screening
Form: Medical History (20)
Generated On: 10 Jun 2021 09:47:59
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Oct 2020 18:50:24

US3752259
Folder: Screening
Form: Medical History (20)
Generated On: 10 Jun 2021 09:47:59
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 18:50:24

US3752259
Folder: Screening
Form: Medical History (20)
Generated On: 10 Jun 2021 09:47:59
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered '0'	(b) (4), (b) (6)	29 Oct 2020 18:50:24

US3752259
Folder: Screening
Form: Medical History (20)
Generated On: 10 Jun 2021 09:47:59
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered 'Jan 2012'	System	19 Nov 2020 16:39:41
User entered 'Jan 2011'	System	29 Oct 2020 18:50:24

US3752259
Folder: Screening
Form: Medical History (20)
Generated On: 10 Jun 2021 09:47:59
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '2012'	System	19 Nov 2020 16:39:41
User entered '2011'	System	29 Oct 2020 18:50:24

FDA-CBER-2022-1614-3180992

US3752259
Folder: Screening
Form: Medical History (20)
Generated On: 10 Jun 2021 09:47:59
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	29 Oct 2020 18:50:24

FDA-CBER-2022-1614-3180993

US3752259
Folder: Screening
Form: Medical History (20)
Generated On: 10 Jun 2021 09:47:59
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	29 Oct 2020 18:50:24

FDA-CBER-2022-1614-3180994

US3752259
Folder: Screening
Form: Medical History (21)
Generated On: 10 Jun 2021 09:47:59
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle related signs and symptoms NEC, PT: Muscle spasms, LLT: Muscle spasms - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 18:54:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 18:54:43
Data point term sent to Coder	System	29 Oct 2020 18:54:13
User entered 'Muscle spasms'	(b) (4), (b) (6)	29 Oct 2020 18:54:00

US3752259
Folder: Screening
Form: Medical History (21)
Generated On: 10 Jun 2021 09:47:59
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered 'un UNK 2017'	(b) (4), (b) (6)	29 Oct 2020 18:54:00

FDA-CBER-2022-1614-3180996

US3752259
Folder: Screening
Form: Medical History (21)
Generated On: 10 Jun 2021 09:47:59
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered '0'	(b) (4), (b) (6)	29 Oct 2020 18:54:00

US3752259
Folder: Screening
Form: Medical History (21)
Generated On: 10 Jun 2021 09:47:59
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Oct 2020 18:54:00

FDA-CBER-2022-1614-3180998

US3752259
Folder: Screening
Form: Medical History (21)
Generated On: 10 Jun 2021 09:47:59
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 18:54:00

US3752259
Folder: Screening
Form: Medical History (21)
Generated On: 10 Jun 2021 09:47:59
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:32:41
User entered '0'	(b) (4), (b) (6)	29 Oct 2020 18:54:00

US3752259
Folder: Screening
Form: Medical History (21)
Generated On: 10 Jun 2021 09:47:59
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered 'Jan 2017'	System	29 Oct 2020 18:54:00

FDA-CBER-2022-1614-3181001

US3752259
Folder: Screening
Form: Medical History (21)
Generated On: 10 Jun 2021 09:47:59
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '2017'	System	29 Oct 2020 18:54:00

FDA-CBER-2022-1614-3181002

US3752259
Folder: Screening
Form: Medical History (21)
Generated On: 10 Jun 2021 09:47:59
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	29 Oct 2020 18:54:00

US3752259
Folder: Screening
Form: Medical History (21)
Generated On: 10 Jun 2021 09:47:59
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	29 Oct 2020 18:54:00

FDA-CBER-2022-1614-3181004

US3752259
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:47:59
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:05:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 15:13:59

US3752259
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:47:59
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:05:42
User entered '26 Aug 2020'	(b) (4), (b) (6)	27 Aug 2020 15:13:59

US3752259
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:47:59
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:05:42
User entered '09:50'	(b) (4), (b) (6)	27 Aug 2020 15:13:59

FDA-CBER-2022-1614-3181007

US3752259
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:47:59
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '26 Aug 2020 09:50'	System	27 Aug 2020 15:13:59

US3752259
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:47:59
Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:05:42
User entered '71' in	(b) (4), (b) (6)	27 Aug 2020 15:13:59
DataPoint set to visible.	System	26 Aug 2020 15:44:23

US3752259
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:47:59
Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:05:42
User entered '190' lb	(b) (4), (b) (6)	27 Aug 2020 15:13:59
DataPoint set to visible.	System	26 Aug 2020 15:44:23

US3752259
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:47:59
BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Amendment Manager: User entered '26.55503'	System	17 Sep 2020 00:03:27
User entered '26.6'	System	27 Aug 2020 15:13:59
DataPoint set to visible.	System	26 Aug 2020 15:44:23

US3752259
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:47:59
BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered 'kg/m2'	System	27 Aug 2020 15:13:59
DataPoint set to visible.	System	26 Aug 2020 15:44:23

US3752259
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:47:59
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:05:42
User entered missing code ND - Not Done.	(b) (4), (b) (6)	27 Aug 2020 15:13:59

US3752259
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:47:59
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:05:42
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:13:59

US3752259
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:47:59
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:05:42
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:13:59

US3752259
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:47:59
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:05:42
User entered missing code ND - Not Done.	(b) (4), (b) (6)	27 Aug 2020 15:13:59

US3752259
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:47:59
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered 'bpm'	System	27 Aug 2020 15:13:59

FDA-CBER-2022-1614-3181017

US3752259
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:47:59
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:05:42
User entered missing code ND - Not Done.	(b) (4), (b) (6)	27 Aug 2020 15:13:59

US3752259
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:47:59
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered 'breaths/min'	System	27 Aug 2020 15:13:59

FDA-CBER-2022-1614-3181019

US3752259
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:47:59
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:05:42
User entered missing code ND - Not Done.	(b) (4), (b) (6)	27 Aug 2020 15:13:59

US3752259
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:47:59
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered 'mmHg'	System	27 Aug 2020 15:13:59

FDA-CBER-2022-1614-3181021

US3752259
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:47:59
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:05:42
User entered missing code ND - Not Done.	(b) (4), (b) (6)	27 Aug 2020 15:13:59

US3752259
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:47:59
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered 'mmHg'	System	27 Aug 2020 15:13:59

FDA-CBER-2022-1614-3181023

US3752259
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:47:59
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04

FDA-CBER-2022-1614-3181024

US3752259
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 09:47:59
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04

FDA-CBER-2022-1614-3181025

US3752259
Folder: Screening
Form: Physical Examination
Generated On: 10 Jun 2021 09:47:59
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:46:54
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 20:26:22
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 20:21:37
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 15:54:56
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 15:14:04

US3752259
Folder: Screening
Form: Physical Examination
Generated On: 10 Jun 2021 09:47:59
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:46:54
User entered '26 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 20:26:22
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 20:21:37
User entered '26 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 15:54:56
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:14:04

US3752259
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:47:59
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 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:44:42
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 15:14:54

US3752259
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:47:59
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 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:44:42
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 15:14:54

US3752259
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:47:59
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 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:44:42
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 15:14:54

US3752259
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:47:59
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 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:44:42
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 15:14:54

US3752259
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:47:59
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 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:44:42
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 15:14:54

US3752259
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:47:59
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 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:44:42
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 15:14:54

US3752259
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:47:59
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 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:44:42
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 15:14:54

US3752259
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:47:59
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 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:44:42
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 15:14:54

US3752259
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:47:59
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 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:44:42
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 15:14:54

US3752259
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:47:59
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 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:44:42
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 15:14:54

US3752259
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:47:59
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 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:44:42
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 15:14:54

US3752259
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:47:59
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 20:11:12
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 17:04:28
DataPoint Un-verified.	(b) (4), (b) (6)	18 Nov 2020 15:45:14
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:44:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 15:14:54

US3752259
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:47:59
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 20:11:18
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 17:04:28
DataPoint Un-verified.	(b) (4), (b) (6)	18 Nov 2020 15:46:25
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 15:44:42
User entered 'Retired'	(b) (4), (b) (6)	27 Aug 2020 15:14:54

US3752259
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:47:59
No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
User entered '1'	(b) (4), (b) (6)	27 Aug 2020 15:14:54

US3752259
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:47:59
Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:44:42
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 15:14:54

US3752259
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:47:59
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 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:44:42
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 15:14:54

US3752259
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:47:59
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 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:44:42
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 15:14:54

US3752259
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:47:59
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 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:44:42
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 15:14:54

US3752259
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:47:59
Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:44:42
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 15:14:54

FDA-CBER-2022-1614-3181046

US3752259
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:47:59
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 15:14:54

US3752259
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 09:47:59
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 15:44:42
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:14:54

FDA-CBER-2022-1614-3181048

US3752259
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 09:47:59
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:35
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:06:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 15:15:09

US3752259
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 09:47:59
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:35
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:06:55
User entered '26 Aug 2020'	(b) (4), (b) (6)	27 Aug 2020 15:15:09

US3752259
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 09:47:59
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 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:35
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:06:55
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	27 Aug 2020 15:15:09

US3752259
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 09:47:59
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:35
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User entered 'VISIT1'	System	27 Aug 2020 15:15:09

US3752259
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:47:59
What was the date of randomization? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:41
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:47:29
User entered '26 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 15:20:55

FDA-CBER-2022-1614-3181053

US3752259
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:47:59
What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:41
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:47:29
User entered '188335'	RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 15:20:55

US3752259
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:47:59
In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:41
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:47:29
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 15:20:55

US3752259
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:47:59
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 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:41
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:47:29
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 15:15:36

US3752259
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:47:59
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 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:10:11
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:41
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User closed query 'Please verify if this is accurate, as source does not mention significant cardiac disease.' (Site from CRA).	(b) (4), (b) (6)	24 Feb 2021 20:55:40
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
Query 'Please verify if this is accurate, as source does not mention significant cardiac disease.' answered with 'The subject has coronary artery disease and is status post coronary artery bypass grafting.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 18:34:15
User opened query 'Please verify if this is accurate, as source does not mention significant cardiac disease.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 18:51:01
DataPoint Un-verified.	(b) (4), (b) (6)	18 Nov 2020 18:48:41
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 18:47:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 15:15:36

US3752259
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:47:59
Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:41
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:47:29
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 15:15:36

US3752259
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:47:59
Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:41
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:47:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 15:15:36

US3752259
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:47:59
Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:41
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:47:29
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 15:15:36

US3752259
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 09:47:59
Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:41
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 18:47:29
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 16:19:29
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 09:46:46
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:01:26

US3752259
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:47:59
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:46
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:22:19
User entered missing code ND - Not Done.	(b) (4), (b) (6)	27 Aug 2020 15:16:58

US3752259
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:47:59
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:46
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:22:19
User entered missing code ND - Not Done.	(b) (4), (b) (6)	27 Aug 2020 15:16:58

US3752259
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:47:59
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:46
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:22:19
User entered missing code ND - Not Done.	(b) (4), (b) (6)	27 Aug 2020 15:16:58

US3752259
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:47:59
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:46
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:22:19
User entered missing code ND - Not Done.	(b) (4), (b) (6)	27 Aug 2020 15:16:58

US3752259
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:47:59
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:46
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	27 Aug 2020 15:16:58

FDA-CBER-2022-1614-3181066

US3752259
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:47:59
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:46
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:22:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 15:16:58

US3752259
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:47:59
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:46
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:22:19
User entered '26 Aug 2020'	(b) (4), (b) (6)	27 Aug 2020 15:16:58

US3752259
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:47:59
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:46
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:22:19
User entered '09:50'	(b) (4), (b) (6)	27 Aug 2020 15:16:58

US3752259
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:47:59
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:46
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User entered '26 Aug 2020 09:50'	System	27 Aug 2020 15:16:58

US3752259
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:47:59
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:46
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:22:19
User entered '97.8' F	(b) (4), (b) (6)	27 Aug 2020 15:16:58

US3752259
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:47:59
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:46
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:22:19
User closed query 'Data is required. Please provide.' (Site from System).	System	27 Aug 2020 15:17:18
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	27 Aug 2020 15:17:18
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Aug 2020 15:17:18
User opened query 'Data is required. Please provide.' (Site from System).	System	27 Aug 2020 15:16:58
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:16:58

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US3752259
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:47:59
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:46
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:22:19
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:16:58

US3752259
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:47:59
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:46
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:22:19
User closed query 'Data is required. Please provide.' (Site from System).	System	27 Aug 2020 15:17:18
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	27 Aug 2020 15:17:18
User entered '62' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Aug 2020 15:17:18
User opened query 'Data is required. Please provide.' (Site from System).	System	27 Aug 2020 15:16:58
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:16:58

US3752259
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:47:59
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:46
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User entered 'bpm'	System	27 Aug 2020 15:17:18
User entered empty.	System	27 Aug 2020 15:16:58

US3752259
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:47:59
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:46
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:22:19
User closed query 'Data is required. Please provide.' (Site from System).	System	27 Aug 2020 15:17:18
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	27 Aug 2020 15:17:18
User entered '22' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Aug 2020 15:17:18
User opened query 'Data is required. Please provide.' (Site from System).	System	27 Aug 2020 15:16:58
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:16:58

FDA-CBER-2022-1614-3181076

US3752259
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:47:59
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:46
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User entered 'breaths/min'	System	27 Aug 2020 15:17:18
User entered empty.	System	27 Aug 2020 15:16:58

US3752259
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:47:59
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:46
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:22:19
User closed query 'Data is required. Please provide.' (Site from System).	System	27 Aug 2020 15:17:18
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	27 Aug 2020 15:17:18
User entered '142' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Aug 2020 15:17:18
User opened query 'Data is required. Please provide.' (Site from System).	System	27 Aug 2020 15:16:58
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:16:58

US3752259
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:47:59
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:46
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User entered 'mmHg'	System	27 Aug 2020 15:17:18
User entered empty.	System	27 Aug 2020 15:16:58

US3752259
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:47:59
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:46
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:22:19
User closed query 'Data is required. Please provide.' (Site from System).	System	27 Aug 2020 15:17:18
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	27 Aug 2020 15:17:18
User entered '62' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Aug 2020 15:17:18
User opened query 'Data is required. Please provide.' (Site from System).	System	27 Aug 2020 15:16:58
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:16:58

US3752259
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:47:59
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:46
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User entered 'mmHg'	System	27 Aug 2020 15:17:18
User entered empty.	System	27 Aug 2020 15:16:58

US3752259
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:47:59
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:46
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:22:19
User entered missing code ND - Not Done.	(b) (4), (b) (6)	27 Aug 2020 15:16:58

US3752259
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 09:47:59
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:46
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:22:19
User entered missing code ND - Not Done.	(b) (4), (b) (6)	27 Aug 2020 15:16:58

US3752259
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:47:59
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:46
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	27 Aug 2020 15:16:58

FDA-CBER-2022-1614-3181084

US3752259
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:47:59
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:46
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:22:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 15:16:58

US3752259
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:47:59
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:46
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:22:19
User entered '26 Aug 2020'	(b) (4), (b) (6)	27 Aug 2020 15:16:58

US3752259
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:47:59
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:46
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:22:19
User entered '11:10'	(b) (4), (b) (6)	27 Aug 2020 15:16:58

US3752259
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:47:59
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:46
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User entered '26 Aug 2020 11:10'	System	27 Aug 2020 15:16:58

US3752259
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:47:59
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:46
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:22:19
User entered '98.0' F	(b) (4), (b) (6)	27 Aug 2020 15:16:58

US3752259
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:47:59
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:46
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:22:19
User closed query 'Data is required. Please provide.' (Site from System).	System	27 Aug 2020 15:17:48
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	27 Aug 2020 15:17:48
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Aug 2020 15:17:48
User opened query 'Data is required. Please provide.' (Site from System).	System	27 Aug 2020 15:16:58
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:16:58

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US3752259
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:47:59
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:46
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:22:19
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:16:58

US3752259
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:47:59
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:46
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:22:19
User closed query 'Data is required. Please provide.' (Site from System).	System	27 Aug 2020 15:17:48
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	27 Aug 2020 15:17:48
User entered '64' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Aug 2020 15:17:48
User opened query 'Data is required. Please provide.' (Site from System).	System	27 Aug 2020 15:16:58
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:16:58

FDA-CBER-2022-1614-3181092

US3752259
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:47:59
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:46
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User entered 'bpm'	System	27 Aug 2020 15:17:48
User entered empty.	System	27 Aug 2020 15:16:58

US3752259
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:47:59
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:46
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:22:19
User closed query 'Data is required. Please provide.' (Site from System).	System	27 Aug 2020 15:17:48
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	27 Aug 2020 15:17:48
User entered '22' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Aug 2020 15:17:48
User opened query 'Data is required. Please provide.' (Site from System).	System	27 Aug 2020 15:16:58
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:16:58

US3752259
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:47:59
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:46
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User entered 'breaths/min'	System	27 Aug 2020 15:17:48
User entered empty.	System	27 Aug 2020 15:16:58

US3752259
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:47:59
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:46
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:22:19
User closed query 'Data is required. Please provide.' (Site from System).	System	27 Aug 2020 15:17:48
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	27 Aug 2020 15:17:48
User entered '148' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Aug 2020 15:17:48
User opened query 'Data is required. Please provide.' (Site from System).	System	27 Aug 2020 15:16:58
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:16:58

US3752259
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:47:59
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:46
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User entered 'mmHg'	System	27 Aug 2020 15:17:48
User entered empty.	System	27 Aug 2020 15:16:58

FDA-CBER-2022-1614-3181097

US3752259
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:47:59
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:46
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:22:19
User closed query 'Data is required. Please provide.' (Site from System).	System	27 Aug 2020 15:17:48
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	27 Aug 2020 15:17:48
User entered '92' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Aug 2020 15:17:48
User opened query 'Data is required. Please provide.' (Site from System).	System	27 Aug 2020 15:16:58
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:16:58

FDA-CBER-2022-1614-3181098

US3752259
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:47:59
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:46
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User entered 'mmHg'	System	27 Aug 2020 15:17:48
User entered empty.	System	27 Aug 2020 15:16:58

US3752259
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 10 Jun 2021 09:47:59
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:50
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:30:29
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 15:55:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 15:18:00

US3752259
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 10 Jun 2021 09:47:59
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:50
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:30:29
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 15:55:12
User entered '26 Aug 2020'	(b) (4), (b) (6)	27 Aug 2020 15:18:00

US3752259
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:47:59
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:53
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:30:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 15:44:50

US3752259
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:47:59
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:53
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:30:40
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 15:44:50

US3752259
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:47:59
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 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:53
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:30:40
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 15:44:50

US3752259
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:47:59
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:53
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User entered 'MRNA-1273 OR PLACEBO'	System	26 Aug 2020 15:44:50

US3752259
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:47:59
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:53
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:30:40
User entered '26 Aug 2020'	(b) (4), (b) (6)	26 Aug 2020 15:44:50

US3752259
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:47:59
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:53
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:30:40
User entered '10:40'	(b) (4), (b) (6)	26 Aug 2020 15:44:50

US3752259
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:47:59
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:53
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User entered '26 Aug 2020 10:40'	System	26 Aug 2020 15:44:50

US3752259
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:47:59
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:53
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:30:40
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	26 Aug 2020 15:44:50

US3752259
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:47:59
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:53
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 19:30:40
User entered 'ONCE'	System	26 Aug 2020 15:44:50

US3752259
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 09:47:59
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:53
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User entered 'INTRAMUSCULAR'	System	26 Aug 2020 15:44:50

US3752259
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:47:59
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:58
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:43:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 15:18:27

US3752259
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:47:59
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:58
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:43:29
User entered '26 Aug 2020'	(b) (4), (b) (6)	27 Aug 2020 15:18:27

US3752259
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:47:59
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:58
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:43:29
User entered '10:00'	(b) (4), (b) (6)	27 Aug 2020 15:18:27

US3752259
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:47:59
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:24:58
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User entered '26 Aug 2020 10:00'	System	27 Aug 2020 15:18:27

US3752259
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 10 Jun 2021 09:47:59
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:25:01
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:44:03
User entered '26 Aug 2020'	(b) (4), (b) (6)	27 Aug 2020 15:18:39

US3752259
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:47:59
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:25:01
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	27 Aug 2020 15:18:39

US3752259
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:47:59
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:11:01
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:25:01
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 15:18:39

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US3752259
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:47:59
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:11:01
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:25:01
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
User entered '09:58'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 15:18:39

US3752259
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:47:59
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:25:01
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User entered '26 Aug 2020 09:58'	System	27 Aug 2020 15:18:39

US3752259
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:47:59
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:25:01
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	27 Aug 2020 15:18:39

FDA-CBER-2022-1614-3181121

US3752259
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:47:59
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:11:01
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:25:01
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 15:18:39

US3752259
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:47:59
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:11:01
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:25:01
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 15:18:39

US3752259
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:47:59
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:25:01
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User entered empty.	System	27 Aug 2020 15:18:39

US3752259
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 10 Jun 2021 09:47:59
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:25:06
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:44:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 15:18:44

US3752259
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 10 Jun 2021 09:47:59
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:25:06
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User entered '1'	System	27 Aug 2020 15:18:44

US3752259
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:47:59
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
Data entry locked.	System	26 Aug 2020 15:44:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 15:44:50

US3752259
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:47:59
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-26T11:00:56', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'ac5ef326-6091-40c5-8b96-444807f3efad'	System	26 Aug 2020 16:01:56
User entered 'Yes (Y)'	System	26 Aug 2020 16:01:56

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US3752259
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:47:59
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-26T11:01:06', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'ac5ef326-6091-40c5-8b96-444807f3efad'	System	26 Aug 2020 16:01:56
User entered '98.0'	System	26 Aug 2020 16:01:56

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US3752259
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:47:59
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-26T11:01:15', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'ac5ef326-6091-40c5-8b96-444807f3efad'	System	26 Aug 2020 16:01:56
User entered 'No (N)'	System	26 Aug 2020 16:01:56

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US3752259
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:47:59
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-26T11:01:25', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'ac5ef326-6091-40c5-8b96-444807f3efad'	System	26 Aug 2020 16:01:56
User entered '26 Aug 2020 11:01'	System	26 Aug 2020 16:01:56

FDA-CBER-2022-1614-3181131

US3752259
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:47:59
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '26 Aug 2020 11:00'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181132

US3752259
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:47:59
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '26 Aug 2020 13:30'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181133

US3752259
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:47:59
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
Data entry locked.	System	26 Aug 2020 15:44:50
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 15:44:50

US3752259
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:47:59
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-26T14:29:50', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'ab884663-dfc4-42df-8af9-9bcddf9a23d1'	System	26 Aug 2020 19:30:38
User entered 'Yes (Y)'	System	26 Aug 2020 19:30:38

FDA-CBER-2022-1614-3181135

US3752259
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:47:59
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-26T14:30:12', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'ab884663-dfc4-42df-8af9-9bcddf9a23d1'	System	26 Aug 2020 19:30:38
User entered '97.7'	System	26 Aug 2020 19:30:38

FDA-CBER-2022-1614-3181136

US3752259
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:47:59
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-26T14:30:17', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'ab884663-dfc4-42df-8af9-9bcddf9a23d1'	System	26 Aug 2020 19:30:38
User entered 'No (N)'	System	26 Aug 2020 19:30:38

FDA-CBER-2022-1614-3181137

US3752259
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:47:59
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-26T14:30:33', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'ab884663-dfc4-42df-8af9-9bcddf9a23d1'	System	26 Aug 2020 19:30:38
User entered '26 Aug 2020 14:30'	System	26 Aug 2020 19:30:38

FDA-CBER-2022-1614-3181138

US3752259
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:47:59
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '26 Aug 2020 14:25'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181139

US3752259
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:47:59
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181140

US3752259
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:47:59
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
Data entry locked.	System	26 Aug 2020 15:44:50
User entered 'Day 2'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181141

US3752259
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:47:59
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-27T12:08:45', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '5e1253b1-68bc-4e43-b0da-bb6003d6125a'	System	27 Aug 2020 17:09:09
User entered 'Yes (Y)'	System	27 Aug 2020 17:09:09

FDA-CBER-2022-1614-3181142

US3752259
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:47:59
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-27T12:08:54', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '5e1253b1-68bc-4e43-b0da-bb6003d6125a'	System	27 Aug 2020 17:09:09
User entered '97.3'	System	27 Aug 2020 17:09:09

FDA-CBER-2022-1614-3181143

US3752259
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:47:59
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-27T12:08:58', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '5e1253b1-68bc-4e43-b0da-bb6003d6125a'	System	27 Aug 2020 17:09:09
User entered 'No (N)'	System	27 Aug 2020 17:09:09

FDA-CBER-2022-1614-3181144

US3752259
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:47:59
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-27T12:09:05', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '5e1253b1-68bc-4e43-b0da-bb6003d6125a'	System	27 Aug 2020 17:09:09
User entered '27 Aug 2020 12:09'	System	27 Aug 2020 17:09:09

FDA-CBER-2022-1614-3181145

US3752259
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:47:59
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181146

US3752259
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:47:59
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181147

US3752259
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:47:59
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
Data entry locked.	System	26 Aug 2020 15:44:50
User entered 'Day 3'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181148

US3752259
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:47:59
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-28T17:10:32', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '993a0676-27d9-40d9-a3df-df864f0c5818'	System	28 Aug 2020 22:10:52
User entered 'Yes (Y)'	System	28 Aug 2020 22:10:52

FDA-CBER-2022-1614-3181149

US3752259
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:47:59
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-28T17:10:38', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '993a0676-27d9-40d9-a3df-df864f0c5818'	System	28 Aug 2020 22:10:52
User entered '97.6'	System	28 Aug 2020 22:10:52

FDA-CBER-2022-1614-3181150

US3752259
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:47:59
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-28T17:10:43', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '993a0676-27d9-40d9-a3df-df864f0c5818'	System	28 Aug 2020 22:10:52
User entered 'No (N)'	System	28 Aug 2020 22:10:52

FDA-CBER-2022-1614-3181151

US3752259
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:47:59
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-28T17:10:48', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '993a0676-27d9-40d9-a3df-df864f0c5818'	System	28 Aug 2020 22:10:52
User entered '28 Aug 2020 17:10'	System	28 Aug 2020 22:10:52

US3752259
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:47:59
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181153

US3752259
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:47:59
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181154

US3752259
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:47:59
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
Data entry locked.	System	26 Aug 2020 15:44:50
User entered 'Day 4'	System	26 Aug 2020 15:44:50

US3752259
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:47:59
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-29T18:03:46', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '9474d9fd-5fb8-45f1-af7d-2c9aefda8161'	System	29 Aug 2020 23:04:06
User entered 'Yes (Y)'	System	29 Aug 2020 23:04:06

FDA-CBER-2022-1614-3181156

US3752259
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:47:59
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-29T18:03:54', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '9474d9fd-5fb8-45f1-af7d-2c9aefda8161'	System	29 Aug 2020 23:04:06
User entered '97.7'	System	29 Aug 2020 23:04:06

FDA-CBER-2022-1614-3181157

US3752259
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:47:59
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-29T18:03:58', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '9474d9fd-5fb8-45f1-af7d-2c9aefda8161'	System	29 Aug 2020 23:04:06
User entered 'No (N)'	System	29 Aug 2020 23:04:06

FDA-CBER-2022-1614-3181158

US3752259
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:47:59
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-29T18:04:03', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '9474d9fd-5fb8-45f1-af7d-2c9aefda8161'	System	29 Aug 2020 23:04:06
User entered '29 Aug 2020 18:04'	System	29 Aug 2020 23:04:06

US3752259
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:47:59
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181160

US3752259
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:47:59
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181161

US3752259
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:47:59
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
Data entry locked.	System	26 Aug 2020 15:44:50
User entered 'Day 5'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181162

US3752259
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:47:59
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-30T18:21:48', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'c871012b-9c3e-48b9-af3f-109f7130e5c9'	System	30 Aug 2020 23:22:05
User entered 'Yes (Y)'	System	30 Aug 2020 23:22:05

FDA-CBER-2022-1614-3181163

US3752259
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:47:59
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-30T18:21:55', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'c871012b-9c3e-48b9-af3f-109f7130e5c9'	System	30 Aug 2020 23:22:05
User entered '97.7'	System	30 Aug 2020 23:22:05

FDA-CBER-2022-1614-3181164

US3752259
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:47:59
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-30T18:21:59', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'c871012b-9c3e-48b9-af3f-109f7130e5c9'	System	30 Aug 2020 23:22:05
User entered 'No (N)'	System	30 Aug 2020 23:22:05

FDA-CBER-2022-1614-3181165

US3752259
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:47:59
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-30T18:22:03', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'c871012b-9c3e-48b9-af3f-109f7130e5c9'	System	30 Aug 2020 23:22:05
User entered '30 Aug 2020 18:22'	System	30 Aug 2020 23:22:05

FDA-CBER-2022-1614-3181166

US3752259
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:47:59
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181167

US3752259
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:47:59
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181168

US3752259
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:47:59
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
Data entry locked.	System	26 Aug 2020 15:44:50
User entered 'Day 6'	System	26 Aug 2020 15:44:50

US3752259
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:47:59
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-31T18:03:56', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '660c5939-5f1d-43cf-bbe4-00440840b8c4'	System	31 Aug 2020 23:04:16
User entered 'Yes (Y)'	System	31 Aug 2020 23:04:16

FDA-CBER-2022-1614-3181170

US3752259
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:47:59
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-31T18:04:03', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '660c5939-5f1d-43cf-bbe4-00440840b8c4'	System	31 Aug 2020 23:04:16
User entered '98.3'	System	31 Aug 2020 23:04:16

FDA-CBER-2022-1614-3181171

US3752259
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:47:59
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-31T18:04:08', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '660c5939-5f1d-43cf-bbe4-00440840b8c4'	System	31 Aug 2020 23:04:16
User entered 'No (N)'	System	31 Aug 2020 23:04:16

FDA-CBER-2022-1614-3181172

US3752259
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:47:59
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-31T18:04:13', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '660c5939-5f1d-43cf-bbe4-00440840b8c4'	System	31 Aug 2020 23:04:16
User entered '31 Aug 2020 18:04'	System	31 Aug 2020 23:04:16

FDA-CBER-2022-1614-3181173

US3752259
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:47:59
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181174

US3752259
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:47:59
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181175

US3752259
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:47:59
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
Data entry locked.	System	26 Aug 2020 15:44:50
User entered 'Day 7'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181176

US3752259
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:47:59
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-01T18:04:22', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'f8de3d75-0d79-4894-aea2-78e1c79d985f'	System	01 Sep 2020 23:04:51
User entered 'Yes (Y)'	System	01 Sep 2020 23:04:51

FDA-CBER-2022-1614-3181177

US3752259
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:47:59
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-01T18:04:35', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'f8de3d75-0d79-4894-aea2-78e1c79d985f'	System	01 Sep 2020 23:04:51
User entered '98.4'	System	01 Sep 2020 23:04:51

FDA-CBER-2022-1614-3181178

US3752259
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:47:59
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-01T18:04:39', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'f8de3d75-0d79-4894-aea2-78e1c79d985f'	System	01 Sep 2020 23:04:51
User entered 'No (N)'	System	01 Sep 2020 23:04:51

FDA-CBER-2022-1614-3181179

US3752259
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:47:59
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-01T18:04:47', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'f8de3d75-0d79-4894-aea2-78e1c79d985f'	System	01 Sep 2020 23:04:51
User entered '01 Sep 2020 18:04'	System	01 Sep 2020 23:04:51

FDA-CBER-2022-1614-3181180

US3752259
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:47:59
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181181

US3752259
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:47:59
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181182

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:47:59
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
Data entry locked.	System	26 Aug 2020 15:44:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 15:44:50

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:47:59
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 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-26T11:03:33', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '795a6ebb-6884-462b-a522-2a0be54706ce'	System	26 Aug 2020 16:03:56
User entered 'None (1)'	System	26 Aug 2020 16:03:56

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:47:59
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-26T11:03:38', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '795a6ebb-6884-462b-a522-2a0be54706ce'	System	26 Aug 2020 16:03:56
User entered 'No (N)'	System	26 Aug 2020 16:03:56

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:47:59
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-26T11:03:41', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '795a6ebb-6884-462b-a522-2a0be54706ce'	System	26 Aug 2020 16:03:56
User entered 'No (N)'	System	26 Aug 2020 16:03:56

FDA-CBER-2022-1614-3181186

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:47:59
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 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-26T11:03:46', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '795a6ebb-6884-462b-a522-2a0be54706ce'	System	26 Aug 2020 16:03:56
User entered 'None (1)'	System	26 Aug 2020 16:03:56

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:47:59
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-26T11:03:50', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '795a6ebb-6884-462b-a522-2a0be54706ce'	System	26 Aug 2020 16:03:56
User entered '26 Aug 2020 11:03'	System	26 Aug 2020 16:03:56

FDA-CBER-2022-1614-3181188

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:47:59
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '26 Aug 2020 11:00'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181189

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:47:59
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '26 Aug 2020 13:30'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181190

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:47:59
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
Data entry locked.	System	26 Aug 2020 15:44:50
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181191

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:47:59
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 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-26T14:30:40', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '60b1e5c7-ac3a-48d9-89a5-96dfb7377a1c'	System	26 Aug 2020 19:31:01
User entered 'None (1)'	System	26 Aug 2020 19:31:01

FDA-CBER-2022-1614-3181192

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:47:59
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-26T14:30:44', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '60b1e5c7-ac3a-48d9-89a5-96dfb7377a1c'	System	26 Aug 2020 19:31:01
User entered 'No (N)'	System	26 Aug 2020 19:31:01

FDA-CBER-2022-1614-3181193

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:47:59
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-26T14:30:48', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '60b1e5c7-ac3a-48d9-89a5-96dfb7377a1c'	System	26 Aug 2020 19:31:01
User entered 'No (N)'	System	26 Aug 2020 19:31:01

FDA-CBER-2022-1614-3181194

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:47:59
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 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-26T14:30:53', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '60b1e5c7-ac3a-48d9-89a5-96dfb7377a1c'	System	26 Aug 2020 19:31:01
User entered 'None (1)'	System	26 Aug 2020 19:31:01

FDA-CBER-2022-1614-3181195

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:47:59
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-26T14:30:58', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '60b1e5c7-ac3a-48d9-89a5-96dfb7377a1c'	System	26 Aug 2020 19:31:01
User entered '26 Aug 2020 14:30'	System	26 Aug 2020 19:31:01

FDA-CBER-2022-1614-3181196

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:47:59
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '26 Aug 2020 14:25'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181197

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:47:59
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181198

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:47:59
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
Data entry locked.	System	26 Aug 2020 15:44:50
User entered 'Day 2'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181199

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:47:59
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 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-27T12:09:11', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '21728a8d-14ee-4357-b22a-3253ebec9559'	System	27 Aug 2020 17:09:32
User entered 'None (1)'	System	27 Aug 2020 17:09:32

FDA-CBER-2022-1614-3181200

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:47:59
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-27T12:09:14', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '21728a8d-14ee-4357-b22a-3253ebec9559'	System	27 Aug 2020 17:09:32
User entered 'No (N)'	System	27 Aug 2020 17:09:32

FDA-CBER-2022-1614-3181201

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:47:59
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-27T12:09:17', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '21728a8d-14ee-4357-b22a-3253ebec9559'	System	27 Aug 2020 17:09:32
User entered 'No (N)'	System	27 Aug 2020 17:09:32

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:47:59
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 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-27T12:09:22', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '21728a8d-14ee-4357-b22a-3253ebec9559'	System	27 Aug 2020 17:09:32
User entered 'None (1)'	System	27 Aug 2020 17:09:32

FDA-CBER-2022-1614-3181203

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:47:59
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-27T12:09:30', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '21728a8d-14ee-4357-b22a-3253ebec9559'	System	27 Aug 2020 17:09:32
User entered '27 Aug 2020 12:09'	System	27 Aug 2020 17:09:32

FDA-CBER-2022-1614-3181204

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:47:59
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181205

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:47:59
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181206

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:47:59
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
Data entry locked.	System	26 Aug 2020 15:44:50
User entered 'Day 3'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181207

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:47:59
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 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-28T17:10:57', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '8a0f42cf-6284-4090-9373-03a6bd8ca983'	System	28 Aug 2020 22:11:16
User entered 'None (1)'	System	28 Aug 2020 22:11:16

FDA-CBER-2022-1614-3181208

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:47:59
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-28T17:11:03', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '8a0f42cf-6284-4090-9373-03a6bd8ca983'	System	28 Aug 2020 22:11:16
User entered 'No (N)'	System	28 Aug 2020 22:11:16

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:47:59
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-28T17:11:05', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '8a0f42cf-6284-4090-9373-03a6bd8ca983'	System	28 Aug 2020 22:11:16
User entered 'No (N)'	System	28 Aug 2020 22:11:16

FDA-CBER-2022-1614-3181210

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:47:59
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 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-28T17:11:09', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '8a0f42cf-6284-4090-9373-03a6bd8ca983'	System	28 Aug 2020 22:11:16
User entered 'None (1)'	System	28 Aug 2020 22:11:16

FDA-CBER-2022-1614-3181211

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:47:59
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-28T17:11:12', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '8a0f42cf-6284-4090-9373-03a6bd8ca983'	System	28 Aug 2020 22:11:16
User entered '28 Aug 2020 17:11'	System	28 Aug 2020 22:11:16

FDA-CBER-2022-1614-3181212

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:47:59
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 15:44:50

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:47:59
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181214

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:47:59
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
Data entry locked.	System	26 Aug 2020 15:44:50
User entered 'Day 4'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181215

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:47:59
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 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-29T18:04:08', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '8275918f-b7b8-403d-9b9e-2096f10fff93'	System	29 Aug 2020 23:04:23
User entered 'None (1)'	System	29 Aug 2020 23:04:23

FDA-CBER-2022-1614-3181216

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:47:59
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-29T18:04:11', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '8275918f-b7b8-403d-9b9e-2096f10fff93'	System	29 Aug 2020 23:04:23
User entered 'No (N)'	System	29 Aug 2020 23:04:23

FDA-CBER-2022-1614-3181217

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:47:59
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-29T18:04:14', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '8275918f-b7b8-403d-9b9e-2096f10fff93'	System	29 Aug 2020 23:04:23
User entered 'No (N)'	System	29 Aug 2020 23:04:23

FDA-CBER-2022-1614-3181218

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:47:59
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 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-29T18:04:17', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '8275918f-b7b8-403d-9b9e-2096f10fff93'	System	29 Aug 2020 23:04:23
User entered 'None (1)'	System	29 Aug 2020 23:04:23

FDA-CBER-2022-1614-3181219

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:47:59
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-29T18:04:20', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '8275918f-b7b8-403d-9b9e-2096f10fff93'	System	29 Aug 2020 23:04:23
User entered '29 Aug 2020 18:04'	System	29 Aug 2020 23:04:23

FDA-CBER-2022-1614-3181220

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:47:59
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181221

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:47:59
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181222

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:47:59
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
Data entry locked.	System	26 Aug 2020 15:44:50
User entered 'Day 5'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181223

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:47:59
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 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-30T18:22:22', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'f13c97ba-c7ce-4eb2-8911-48873a169470'	System	30 Aug 2020 23:22:37
User entered 'None (1)'	System	30 Aug 2020 23:22:37

FDA-CBER-2022-1614-3181224

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:47:59
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-30T18:22:25', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'f13c97ba-c7ce-4eb2-8911-48873a169470'	System	30 Aug 2020 23:22:37
User entered 'No (N)'	System	30 Aug 2020 23:22:37

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:47:59
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-30T18:22:28', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'f13c97ba-c7ce-4eb2-8911-48873a169470'	System	30 Aug 2020 23:22:37
User entered 'No (N)'	System	30 Aug 2020 23:22:37

FDA-CBER-2022-1614-3181226

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:47:59
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 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-30T18:22:32', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'f13c97ba-c7ce-4eb2-8911-48873a169470'	System	30 Aug 2020 23:22:37
User entered 'None (1)'	System	30 Aug 2020 23:22:37

FDA-CBER-2022-1614-3181227

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:47:59
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-30T18:22:35', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'f13c97ba-c7ce-4eb2-8911-48873a169470'	System	30 Aug 2020 23:22:37
User entered '30 Aug 2020 18:22'	System	30 Aug 2020 23:22:37

FDA-CBER-2022-1614-3181228

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:47:59
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181229

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:47:59
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181230

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:47:59
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
Data entry locked.	System	26 Aug 2020 15:44:50
User entered 'Day 6'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181231

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:47:59
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 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-31T18:04:26', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '8a088a76-d3eb-485d-b4a7-fe4bf1146ed0'	System	31 Aug 2020 23:04:49
User entered 'Does not interfere with activity (2)'	System	31 Aug 2020 23:04:49

FDA-CBER-2022-1614-3181232

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:47:59
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-31T18:04:29', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '8a088a76-d3eb-485d-b4a7-fe4bf1146ed0'	System	31 Aug 2020 23:04:49
User entered 'No (N)'	System	31 Aug 2020 23:04:49

FDA-CBER-2022-1614-3181233

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:47:59
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-31T18:04:32', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '8a088a76-d3eb-485d-b4a7-fe4bf1146ed0'	System	31 Aug 2020 23:04:49
User entered 'No (N)'	System	31 Aug 2020 23:04:49

FDA-CBER-2022-1614-3181234

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:47:59
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 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-31T18:04:37', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '8a088a76-d3eb-485d-b4a7-fe4bf1146ed0'	System	31 Aug 2020 23:04:49
User entered 'None (1)'	System	31 Aug 2020 23:04:49

FDA-CBER-2022-1614-3181235

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:47:59
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-31T18:04:41', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '8a088a76-d3eb-485d-b4a7-fe4bf1146ed0'	System	31 Aug 2020 23:04:49
User entered '31 Aug 2020 18:04'	System	31 Aug 2020 23:04:49

FDA-CBER-2022-1614-3181236

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:47:59
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181237

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:47:59
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181238

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:47:59
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
Data entry locked.	System	26 Aug 2020 15:44:50
User entered 'Day 7'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181239

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:47:59
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 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-01T18:04:52', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '535cc159-0302-4192-962e-a9bb1d48b124'	System	01 Sep 2020 23:05:11
User entered 'None (1)'	System	01 Sep 2020 23:05:11

FDA-CBER-2022-1614-3181240

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:47:59
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-01T18:04:56', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '535cc159-0302-4192-962e-a9bb1d48b124'	System	01 Sep 2020 23:05:11
User entered 'No (N)'	System	01 Sep 2020 23:05:11

FDA-CBER-2022-1614-3181241

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:47:59
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-01T18:04:58', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '535cc159-0302-4192-962e-a9bb1d48b124'	System	01 Sep 2020 23:05:11
User entered 'No (N)'	System	01 Sep 2020 23:05:11

FDA-CBER-2022-1614-3181242

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:47:59
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 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-01T18:05:02', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '535cc159-0302-4192-962e-a9bb1d48b124'	System	01 Sep 2020 23:05:11
User entered 'None (1)'	System	01 Sep 2020 23:05:11

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:47:59
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-01T18:05:09', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '535cc159-0302-4192-962e-a9bb1d48b124'	System	01 Sep 2020 23:05:11
User entered '01 Sep 2020 18:05'	System	01 Sep 2020 23:05:11

FDA-CBER-2022-1614-3181244

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:47:59
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181245

US3752259
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:47:59
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181246

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:47:59
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
Data entry locked.	System	26 Aug 2020 15:44:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181247

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:47:59
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-26T11:04:46', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '08dc85c7-4b34-4fc1-9a13-6d921d945444'	System	26 Aug 2020 16:05:16
User entered 'None (0)'	System	26 Aug 2020 16:05:16

FDA-CBER-2022-1614-3181248

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:47:59
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-26T11:04:53', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '08dc85c7-4b34-4fc1-9a13-6d921d945444'	System	26 Aug 2020 16:05:16
User entered 'None (0)'	System	26 Aug 2020 16:05:16

FDA-CBER-2022-1614-3181249

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:47:59
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-26T11:04:56', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '08dc85c7-4b34-4fc1-9a13-6d921d945444'	System	26 Aug 2020 16:05:16
User entered 'None (0)'	System	26 Aug 2020 16:05:16

FDA-CBER-2022-1614-3181250

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:47:59
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-26T11:04:59', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '08dc85c7-4b34-4fc1-9a13-6d921d945444'	System	26 Aug 2020 16:05:16
User entered 'None (0)'	System	26 Aug 2020 16:05:16

FDA-CBER-2022-1614-3181251

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:47:59
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-26T11:05:02', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '08dc85c7-4b34-4fc1-9a13-6d921d945444'	System	26 Aug 2020 16:05:16
User entered 'None (0)'	System	26 Aug 2020 16:05:16

FDA-CBER-2022-1614-3181252

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:47:59
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-26T11:05:04', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '08dc85c7-4b34-4fc1-9a13-6d921d945444'	System	26 Aug 2020 16:05:16
User entered 'None (0)'	System	26 Aug 2020 16:05:16

FDA-CBER-2022-1614-3181253

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:47:59
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 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-26T11:05:08', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '08dc85c7-4b34-4fc1-9a13-6d921d945444'	System	26 Aug 2020 16:05:16
User entered 'No (N)'	System	26 Aug 2020 16:05:16

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:47:59
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-26T11:05:12', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '08dc85c7-4b34-4fc1-9a13-6d921d945444'	System	26 Aug 2020 16:05:16
User entered '26 Aug 2020 11:05'	System	26 Aug 2020 16:05:16

FDA-CBER-2022-1614-3181255

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:47:59
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '26 Aug 2020 11:00'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181256

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:47:59
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '26 Aug 2020 13:30'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181257

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:47:59
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
Data entry locked.	System	26 Aug 2020 15:44:50
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181258

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:47:59
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-26T14:31:04', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '00a07f64-0663-44e6-a336-b007b23ab27b'	System	26 Aug 2020 19:31:38
User entered 'None (0)'	System	26 Aug 2020 19:31:38

FDA-CBER-2022-1614-3181259

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:47:59
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-26T14:31:06', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '00a07f64-0663-44e6-a336-b007b23ab27b'	System	26 Aug 2020 19:31:38
User entered 'None (0)'	System	26 Aug 2020 19:31:38

FDA-CBER-2022-1614-3181260

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:47:59
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-26T14:31:12', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '00a07f64-0663-44e6-a336-b007b23ab27b'	System	26 Aug 2020 19:31:38
User entered 'None (0)'	System	26 Aug 2020 19:31:38

FDA-CBER-2022-1614-3181261

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:47:59
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-26T14:31:22', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '00a07f64-0663-44e6-a336-b007b23ab27b'	System	26 Aug 2020 19:31:38
User entered 'None (0)'	System	26 Aug 2020 19:31:38

FDA-CBER-2022-1614-3181262

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:47:59
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-26T14:31:25', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '00a07f64-0663-44e6-a336-b007b23ab27b'	System	26 Aug 2020 19:31:38
User entered 'None (0)'	System	26 Aug 2020 19:31:38

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:47:59
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-26T14:31:29', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '00a07f64-0663-44e6-a336-b007b23ab27b'	System	26 Aug 2020 19:31:38
User entered 'None (0)'	System	26 Aug 2020 19:31:38

FDA-CBER-2022-1614-3181264

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:47:59
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 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-26T14:31:32', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '00a07f64-0663-44e6-a336-b007b23ab27b'	System	26 Aug 2020 19:31:38
User entered 'No (N)'	System	26 Aug 2020 19:31:38

FDA-CBER-2022-1614-3181265

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:47:59
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-26T14:31:36', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '00a07f64-0663-44e6-a336-b007b23ab27b'	System	26 Aug 2020 19:31:38
User entered '26 Aug 2020 14:31'	System	26 Aug 2020 19:31:38

FDA-CBER-2022-1614-3181266

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:47:59
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '26 Aug 2020 14:25'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181267

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:47:59
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181268

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:47:59
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
Data entry locked.	System	26 Aug 2020 15:44:50
User entered 'Day 2'	System	26 Aug 2020 15:44:50

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:47:59
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-27T12:09:35', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '4781321f-480e-471e-87b1-38dab2609d1a'	System	27 Aug 2020 17:10:08
User entered 'None (0)'	System	27 Aug 2020 17:10:08

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:47:59
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-27T12:09:38', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '4781321f-480e-471e-87b1-38dab2609d1a'	System	27 Aug 2020 17:10:08
User entered 'None (0)'	System	27 Aug 2020 17:10:08

FDA-CBER-2022-1614-3181271

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:47:59
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-27T12:09:40', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '4781321f-480e-471e-87b1-38dab2609d1a'	System	27 Aug 2020 17:10:08
User entered 'None (0)'	System	27 Aug 2020 17:10:08

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:47:59
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-27T12:09:43', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '4781321f-480e-471e-87b1-38dab2609d1a'	System	27 Aug 2020 17:10:08
User entered 'None (0)'	System	27 Aug 2020 17:10:08

FDA-CBER-2022-1614-3181273

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:47:59
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-27T12:09:46', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '4781321f-480e-471e-87b1-38dab2609d1a'	System	27 Aug 2020 17:10:08
User entered 'None (0)'	System	27 Aug 2020 17:10:08

FDA-CBER-2022-1614-3181274

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:47:59
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-27T12:09:49', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '4781321f-480e-471e-87b1-38dab2609d1a'	System	27 Aug 2020 17:10:08
User entered 'None (0)'	System	27 Aug 2020 17:10:08

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:47:59
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 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-27T12:09:53', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '4781321f-480e-471e-87b1-38dab2609d1a'	System	27 Aug 2020 17:10:08
User entered 'No (N)'	System	27 Aug 2020 17:10:08

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:47:59
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-27T12:10:02', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '4781321f-480e-471e-87b1-38dab2609d1a'	System	27 Aug 2020 17:10:08
User entered '27 Aug 2020 12:10'	System	27 Aug 2020 17:10:08

FDA-CBER-2022-1614-3181277

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:47:59
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181278

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:47:59
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181279

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:47:59
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
Data entry locked.	System	26 Aug 2020 15:44:50
User entered 'Day 3'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181280

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:47:59
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-28T17:11:17', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '60f99b7c-b4c1-4bcc-8a19-1df0e32cff0e'	System	28 Aug 2020 22:11:36
User entered 'None (0)'	System	28 Aug 2020 22:11:36

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:47:59
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-28T17:11:19', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '60f99b7c-b4c1-4bcc-8a19-1df0e32cff0e'	System	28 Aug 2020 22:11:36
User entered 'None (0)'	System	28 Aug 2020 22:11:36

FDA-CBER-2022-1614-3181282

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:47:59
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-28T17:11:21', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '60f99b7c-b4c1-4bcc-8a19-1df0e32cff0e'	System	28 Aug 2020 22:11:36
User entered 'None (0)'	System	28 Aug 2020 22:11:36

FDA-CBER-2022-1614-3181283

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:47:59
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-28T17:11:23', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '60f99b7c-b4c1-4bcc-8a19-1df0e32cff0e'	System	28 Aug 2020 22:11:36
User entered 'None (0)'	System	28 Aug 2020 22:11:36

FDA-CBER-2022-1614-3181284

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:47:59
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-28T17:11:25', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '60f99b7c-b4c1-4bcc-8a19-1df0e32cff0e'	System	28 Aug 2020 22:11:36
User entered 'None (0)'	System	28 Aug 2020 22:11:36

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:47:59
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-28T17:11:27', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '60f99b7c-b4c1-4bcc-8a19-1df0e32cff0e'	System	28 Aug 2020 22:11:36
User entered 'None (0)'	System	28 Aug 2020 22:11:36

FDA-CBER-2022-1614-3181286

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:47:59
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 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-28T17:11:31', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '60f99b7c-b4c1-4bcc-8a19-1df0e32cff0e'	System	28 Aug 2020 22:11:36
User entered 'No (N)'	System	28 Aug 2020 22:11:36

FDA-CBER-2022-1614-3181287

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:47:59
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-28T17:11:34', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '60f99b7c-b4c1-4bcc-8a19-1df0e32cff0e'	System	28 Aug 2020 22:11:36
User entered '28 Aug 2020 17:11'	System	28 Aug 2020 22:11:36

FDA-CBER-2022-1614-3181288

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:47:59
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 15:44:50

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:47:59
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181290

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:47:59
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
Data entry locked.	System	26 Aug 2020 15:44:50
User entered 'Day 4'	System	26 Aug 2020 15:44:50

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:47:59
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-29T18:04:25', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'a1421530-8647-4495-822d-7df0afa58103'	System	29 Aug 2020 23:04:50
User entered 'None (0)'	System	29 Aug 2020 23:04:50

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:47:59
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-29T18:04:27', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'a1421530-8647-4495-822d-7df0afa58103'	System	29 Aug 2020 23:04:50
User entered 'None (0)'	System	29 Aug 2020 23:04:50

FDA-CBER-2022-1614-3181293

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:47:59
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-29T18:04:29', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'a1421530-8647-4495-822d-7df0afa58103'	System	29 Aug 2020 23:04:50
User entered 'None (0)'	System	29 Aug 2020 23:04:50

FDA-CBER-2022-1614-3181294

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:47:59
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-29T18:04:32', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'a1421530-8647-4495-822d-7df0afa58103'	System	29 Aug 2020 23:04:50
User entered 'None (0)'	System	29 Aug 2020 23:04:50

FDA-CBER-2022-1614-3181295

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:47:59
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-29T18:04:37', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'a1421530-8647-4495-822d-7df0afa58103'	System	29 Aug 2020 23:04:50
User entered 'None (0)'	System	29 Aug 2020 23:04:50

FDA-CBER-2022-1614-3181296

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:47:59
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-29T18:04:41', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'a1421530-8647-4495-822d-7df0afa58103'	System	29 Aug 2020 23:04:50
User entered 'None (0)'	System	29 Aug 2020 23:04:50

FDA-CBER-2022-1614-3181297

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:47:59
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 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-29T18:04:44', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'a1421530-8647-4495-822d-7df0afa58103'	System	29 Aug 2020 23:04:50
User entered 'No (N)'	System	29 Aug 2020 23:04:50

FDA-CBER-2022-1614-3181298

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:47:59
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-29T18:04:46', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'a1421530-8647-4495-822d-7df0afa58103'	System	29 Aug 2020 23:04:50
User entered '29 Aug 2020 18:04'	System	29 Aug 2020 23:04:50

FDA-CBER-2022-1614-3181299

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:47:59
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181300

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:47:59
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 15:44:50

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:47:59
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
Data entry locked.	System	26 Aug 2020 15:44:50
User entered 'Day 5'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181302

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:47:59
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-30T18:22:43', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '9565d164-206b-46f8-a522-3ad9305a910e'	System	30 Aug 2020 23:23:05
User entered 'None (0)'	System	30 Aug 2020 23:23:05

FDA-CBER-2022-1614-3181303

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:47:59
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-30T18:22:46', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '9565d164-206b-46f8-a522-3ad9305a910e'	System	30 Aug 2020 23:23:05
User entered 'None (0)'	System	30 Aug 2020 23:23:05

FDA-CBER-2022-1614-3181304

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:47:59
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-30T18:22:49', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '9565d164-206b-46f8-a522-3ad9305a910e'	System	30 Aug 2020 23:23:05
User entered 'None (0)'	System	30 Aug 2020 23:23:05

FDA-CBER-2022-1614-3181305

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:47:59
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-30T18:22:52', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '9565d164-206b-46f8-a522-3ad9305a910e'	System	30 Aug 2020 23:23:05
User entered 'None (0)'	System	30 Aug 2020 23:23:05

FDA-CBER-2022-1614-3181306

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:47:59
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-30T18:22:54', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '9565d164-206b-46f8-a522-3ad9305a910e'	System	30 Aug 2020 23:23:05
User entered 'None (0)'	System	30 Aug 2020 23:23:05

FDA-CBER-2022-1614-3181307

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:47:59
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-30T18:22:57', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '9565d164-206b-46f8-a522-3ad9305a910e'	System	30 Aug 2020 23:23:05
User entered 'None (0)'	System	30 Aug 2020 23:23:05

FDA-CBER-2022-1614-3181308

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:47:59
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 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-30T18:23:01', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '9565d164-206b-46f8-a522-3ad9305a910e'	System	30 Aug 2020 23:23:05
User entered 'No (N)'	System	30 Aug 2020 23:23:05

FDA-CBER-2022-1614-3181309

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:47:59
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-30T18:23:04', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '9565d164-206b-46f8-a522-3ad9305a910e'	System	30 Aug 2020 23:23:05
User entered '30 Aug 2020 18:23'	System	30 Aug 2020 23:23:05

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:47:59
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 15:44:50

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:47:59
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181312

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:47:59
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
Data entry locked.	System	26 Aug 2020 15:44:50
User entered 'Day 6'	System	26 Aug 2020 15:44:50

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:47:59
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-31T18:04:45', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'c260207b-a885-48af-9289-9388ec11ff91'	System	31 Aug 2020 23:05:10
User entered 'None (0)'	System	31 Aug 2020 23:05:10

FDA-CBER-2022-1614-3181314

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:47:59
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-31T18:04:48', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'c260207b-a885-48af-9289-9388ec11ff91'	System	31 Aug 2020 23:05:10
User entered 'None (0)'	System	31 Aug 2020 23:05:10

FDA-CBER-2022-1614-3181315

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:47:59
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-31T18:04:50', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'c260207b-a885-48af-9289-9388ec11ff91'	System	31 Aug 2020 23:05:10
User entered 'None (0)'	System	31 Aug 2020 23:05:10

FDA-CBER-2022-1614-3181316

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:47:59
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-31T18:04:53', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'c260207b-a885-48af-9289-9388ec11ff91'	System	31 Aug 2020 23:05:10
User entered 'None (0)'	System	31 Aug 2020 23:05:10

FDA-CBER-2022-1614-3181317

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:47:59
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-31T18:04:56', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'c260207b-a885-48af-9289-9388ec11ff91'	System	31 Aug 2020 23:05:10
User entered 'None (0)'	System	31 Aug 2020 23:05:10

FDA-CBER-2022-1614-3181318

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:47:59
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-31T18:04:58', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'c260207b-a885-48af-9289-9388ec11ff91'	System	31 Aug 2020 23:05:10
User entered 'None (0)'	System	31 Aug 2020 23:05:10

FDA-CBER-2022-1614-3181319

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:47:59
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 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-31T18:05:02', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'c260207b-a885-48af-9289-9388ec11ff91'	System	31 Aug 2020 23:05:10
User entered 'No (N)'	System	31 Aug 2020 23:05:10

FDA-CBER-2022-1614-3181320

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:47:59
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-08-31T18:05:09', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'c260207b-a885-48af-9289-9388ec11ff91'	System	31 Aug 2020 23:05:10
User entered '31 Aug 2020 18:05'	System	31 Aug 2020 23:05:10

FDA-CBER-2022-1614-3181321

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:47:59
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181322

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:47:59
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181323

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:47:59
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
Data entry locked.	System	26 Aug 2020 15:44:50
User entered 'Day 7'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181324

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:47:59
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-01T18:05:16', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'cbbca5ba-0a43-4654-b0ba-7523825303d6'	System	01 Sep 2020 23:05:41
User entered 'None (0)'	System	01 Sep 2020 23:05:41

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:47:59
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-01T18:05:19', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'cbbca5ba-0a43-4654-b0ba-7523825303d6'	System	01 Sep 2020 23:05:41
User entered 'None (0)'	System	01 Sep 2020 23:05:41

FDA-CBER-2022-1614-3181326

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:47:59
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-01T18:05:22', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'cbbca5ba-0a43-4654-b0ba-7523825303d6'	System	01 Sep 2020 23:05:41
User entered 'None (0)'	System	01 Sep 2020 23:05:41

FDA-CBER-2022-1614-3181327

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:47:59
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-01T18:05:24', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'cbbca5ba-0a43-4654-b0ba-7523825303d6'	System	01 Sep 2020 23:05:41
User entered 'None (0)'	System	01 Sep 2020 23:05:41

FDA-CBER-2022-1614-3181328

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:47:59
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-01T18:05:27', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'cbbca5ba-0a43-4654-b0ba-7523825303d6'	System	01 Sep 2020 23:05:41
User entered 'None (0)'	System	01 Sep 2020 23:05:41

FDA-CBER-2022-1614-3181329

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:47:59
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-01T18:05:31', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'cbbca5ba-0a43-4654-b0ba-7523825303d6'	System	01 Sep 2020 23:05:41
User entered 'None (0)'	System	01 Sep 2020 23:05:41

FDA-CBER-2022-1614-3181330

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:47:59
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 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-01T18:05:35', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'cbbca5ba-0a43-4654-b0ba-7523825303d6'	System	01 Sep 2020 23:05:41
User entered 'No (N)'	System	01 Sep 2020 23:05:41

FDA-CBER-2022-1614-3181331

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:47:59
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-01T18:05:38', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'cbbca5ba-0a43-4654-b0ba-7523825303d6'	System	01 Sep 2020 23:05:41
User entered '01 Sep 2020 18:05'	System	01 Sep 2020 23:05:41

FDA-CBER-2022-1614-3181332

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:47:59
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181333

US3752259
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:47:59
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181334

US3752259
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:47:59
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:25:11
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:45:20
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	23 Sep 2020 14:33:29

US3752259
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:47:59
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:25:11
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:45:20
User entered '2 Sep 2020'	Amanda Horn (b) (4) (b) (4)	23 Sep 2020 14:33:29

US3752259
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:47:59
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:25:11
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:45:20
User entered 'Contact Made (CONTACT MADE)'	Amanda Horn (b) (4) (b) (4)	23 Sep 2020 14:33:29

US3752259
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:47:59
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:25:11
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 19:45:20
User entered empty.	Amanda Horn (b) (4) (b) (4)	23 Sep 2020 14:33:29

FDA-CBER-2022-1614-3181338

US3752259
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:47:59
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:25:18
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:52:23
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	23 Sep 2020 14:33:35

US3752259
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:47:59
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:25:18
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User entered '1'	System	23 Sep 2020 14:33:35

US3752259
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:47:59
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:25:22
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:52:45
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	23 Sep 2020 14:33:44

FDA-CBER-2022-1614-3181341

US3752259
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:47:59
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:25:22
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:52:45
User entered '9 Sep 2020'	Amanda Horn (b) (4) (b) (4)	23 Sep 2020 14:33:44

US3752259
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:47:59
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:25:22
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:52:45
User entered 'Contact Made (CONTACT MADE)'	Amanda Horn (b) (4) (b) (4)	23 Sep 2020 14:33:44

US3752259
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:47:59
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:25:22
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 19:52:45
User entered empty.	Amanda Horn (b) (4) (b) (4)	23 Sep 2020 14:33:44

US3752259
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:47:59
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:25:25
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:04:08
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	23 Sep 2020 14:33:49

US3752259
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:47:59
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Data hard unlocked.	(b) (4), (b) (6)	08 Apr 2021 13:25:25
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:14:20
User entered '1'	System	23 Sep 2020 14:33:49

US3752259
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:47:59
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:04:21
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	23 Sep 2020 14:33:59

US3752259
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:47:59
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:04:21
User entered '16 Sep 2020'	Amanda Horn (b) (4) (b) (4)	23 Sep 2020 14:33:59

US3752259
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:47:59
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:04:21
User entered 'Contact Made (CONTACT MADE)'	Amanda Horn (b) (4) (b) (4)	23 Sep 2020 14:33:59

US3752259
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:47:59
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:04:21
User entered empty.	Amanda Horn (b) (4) (b) (4)	23 Sep 2020 14:33:59

US3752259
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:47:59
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:45:34
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	23 Sep 2020 14:34:09

US3752259
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:47:59
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '1'	System	23 Sep 2020 14:34:09

FDA-CBER-2022-1614-3181352

US3752259
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:47:59
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:51:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 15:13:20

US3752259
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:47:59
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:51:41
User entered '23 Sep 2020'	(b) (4), (b) (6)	23 Sep 2020 15:13:20

US3752259
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:47:59
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 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:51:42
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	23 Sep 2020 15:13:20

US3752259
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:47:59
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered 'VISIT2'	System	23 Sep 2020 15:13:20

FDA-CBER-2022-1614-3181356

US3752259
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:47:59
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	24 Sep 2020 16:20:15

FDA-CBER-2022-1614-3181357

US3752259
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:47:59
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:52:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 16:20:15

US3752259
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:47:59
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:52:43
User entered '23 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 16:20:15

US3752259
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:47:59
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:52:45
User entered '09:17'	(b) (4), (b) (6)	24 Sep 2020 16:20:15

FDA-CBER-2022-1614-3181360

US3752259
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:47:59
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '23 Sep 2020 09:17'	System	24 Sep 2020 16:20:15

FDA-CBER-2022-1614-3181361

US3752259
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:47:59
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:52:50
User entered '97.8' F	(b) (4), (b) (6)	24 Sep 2020 16:20:15

US3752259
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:47:59
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:52:54
User closed query 'Data is required. Please provide.' (Site from System).	System	24 Sep 2020 16:20:39
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	24 Sep 2020 16:20:39
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 16:20:39
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Sep 2020 16:20:15
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 16:20:15

US3752259
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:47:59
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:52:57
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 16:20:15

US3752259
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:47:59
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:52:59
User closed query 'Data is required. Please provide.' (Site from System).	System	24 Sep 2020 16:20:39
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	24 Sep 2020 16:20:39
User entered '64' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 16:20:39
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Sep 2020 16:20:15
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 16:20:15

US3752259
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:47:59
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered 'bpm'	System	24 Sep 2020 16:20:39
User entered empty.	System	24 Sep 2020 16:20:15

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US3752259
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:47:59
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:53:01
User closed query 'Data is required. Please provide.' (Site from System).	System	24 Sep 2020 16:20:39
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	24 Sep 2020 16:20:39
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 16:20:39
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Sep 2020 16:20:15
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 16:20:15

US3752259
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:47:59
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered 'breaths/min'	System	24 Sep 2020 16:20:39
User entered empty.	System	24 Sep 2020 16:20:15

US3752259
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:47:59
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:53:04
User closed query 'Data is required. Please provide.' (Site from System).	System	24 Sep 2020 16:20:39
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	24 Sep 2020 16:20:39
User entered '150' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 16:20:39
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Sep 2020 16:20:15
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 16:20:15

US3752259
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:47:59
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered 'mmHg'	System	24 Sep 2020 16:20:39
User entered empty.	System	24 Sep 2020 16:20:15

US3752259
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:47:59
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:53:06
User closed query 'Data is required. Please provide.' (Site from System).	System	24 Sep 2020 16:20:39
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	24 Sep 2020 16:20:39
User entered '70' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 16:20:39
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Sep 2020 16:20:15
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 16:20:15

US3752259
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 09:47:59
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered 'mmHg'	System	24 Sep 2020 16:20:39
User entered empty.	System	24 Sep 2020 16:20:15

US3752259
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:47:59
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	24 Sep 2020 16:20:15

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US3752259
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:47:59
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:53:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 16:20:15

US3752259
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:47:59
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:53:26
User entered '23 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 16:20:15

US3752259
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:47:59
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:53:28
User closed query 'Data is required. Please provide.' (Site from System).	System	24 Sep 2020 16:21:16
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	24 Sep 2020 16:21:16
User entered '10:25' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 16:21:16
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Sep 2020 16:20:15
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 16:20:15

US3752259
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:47:59
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '23 Sep 2020 10:25'	System	24 Sep 2020 16:21:16
User entered empty.	System	24 Sep 2020 16:20:15

US3752259
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:47:59
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:53:30
User closed query 'Data is required. Please provide.' (Site from System).	System	24 Sep 2020 16:21:16
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	24 Sep 2020 16:21:16
User entered '98.8' F reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 16:21:16
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Sep 2020 16:20:15
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 16:20:15

US3752259
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:47:59
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:53:33
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 16:21:16
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 16:20:15

US3752259
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:47:59
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:53:34
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 16:20:15

US3752259
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:47:59
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:53:39
User closed query 'Data is required. Please provide.' (Site from System).	System	24 Sep 2020 16:21:16
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	24 Sep 2020 16:21:16
User entered '66' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 16:21:16
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Sep 2020 16:20:15
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 16:20:15

US3752259
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:47:59
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered 'bpm'	System	24 Sep 2020 16:21:16
User entered empty.	System	24 Sep 2020 16:20:15

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US3752259
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:47:59
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:53:42
User closed query 'Data is required. Please provide.' (Site from System).	System	24 Sep 2020 16:21:16
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	24 Sep 2020 16:21:16
User entered '18' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 16:21:16
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Sep 2020 16:20:15
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 16:20:15

US3752259
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:47:59
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered 'breaths/min'	System	24 Sep 2020 16:21:16
User entered empty.	System	24 Sep 2020 16:20:15

US3752259
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:47:59
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:53:47
User closed query 'Data is required. Please provide.' (Site from System).	System	24 Sep 2020 16:21:16
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	24 Sep 2020 16:21:16
User entered '140' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 16:21:16
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Sep 2020 16:20:15
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 16:20:15

US3752259
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:47:59
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered 'mmHg'	System	24 Sep 2020 16:21:16
User entered empty.	System	24 Sep 2020 16:20:15

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US3752259
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:47:59
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:53:49
User closed query 'Data is required. Please provide.' (Site from System).	System	24 Sep 2020 16:21:16
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	24 Sep 2020 16:21:16
User entered '72' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 16:21:16
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Sep 2020 16:20:15
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 16:20:15

US3752259
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 09:47:59
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered 'mmHg'	System	24 Sep 2020 16:21:16
User entered empty.	System	24 Sep 2020 16:20:15

US3752259
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:47:59
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:54:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 16:21:27

US3752259
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:47:59
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:54:15
User entered '23 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 16:21:27

US3752259
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:47:59
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:51:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 15:13:44

US3752259
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:47:59
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:52:00
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 15:13:44

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US3752259
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:47:59
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 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:52:02
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 15:13:44

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US3752259
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:47:59
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered 'MRNA-1273 OR PLACEBO'	System	23 Sep 2020 15:13:44

US3752259
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:47:59
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:52:06
User entered '23 Sep 2020'	(b) (4), (b) (6)	23 Sep 2020 15:13:44

US3752259
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:47:59
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:52:07
User entered '10:10'	(b) (4), (b) (6)	23 Sep 2020 15:13:44

US3752259
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:47:59
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '23 Sep 2020 10:10'	System	23 Sep 2020 15:13:44

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US3752259
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:47:59
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:52:10
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	23 Sep 2020 15:13:44

US3752259
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:47:59
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 15:52:12
User entered 'ONCE'	System	23 Sep 2020 15:13:44

US3752259
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 09:47:59
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered 'INTRAMUSCULAR'	System	23 Sep 2020 15:13:44

FDA-CBER-2022-1614-3181400

US3752259
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:47:59
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:54:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 16:21:42

US3752259
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:47:59
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:54:39
User entered '23 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 16:21:42

US3752259
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:47:59
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:54:40
User entered '09:22'	(b) (4), (b) (6)	24 Sep 2020 16:21:42

US3752259
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:47:59
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '23 Sep 2020 09:22'	System	24 Sep 2020 16:21:42

FDA-CBER-2022-1614-3181404

US3752259
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 10 Jun 2021 09:47:59
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:54:53
User entered '23 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 16:22:02

US3752259
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:47:59
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	24 Sep 2020 16:22:02

US3752259
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:47:59
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:54:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 16:22:02

US3752259
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:47:59
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:54:58
User entered '09:19'	(b) (4), (b) (6)	24 Sep 2020 16:22:02

FDA-CBER-2022-1614-3181408

US3752259
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 09:47:59
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '23 Sep 2020 09:19'	System	24 Sep 2020 16:22:02

FDA-CBER-2022-1614-3181409

US3752259
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:47:59
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	24 Sep 2020 16:22:02

US3752259
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:47:59
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:55:14
User entered 'No (N)'	(b) (4), (b) (6)	24 Sep 2020 16:22:02

US3752259
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:47:59
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:55:16
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 16:22:02

FDA-CBER-2022-1614-3181412

US3752259
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 09:47:59
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	24 Sep 2020 16:22:02

FDA-CBER-2022-1614-3181413

US3752259
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:47:59
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:55:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 16:22:07

US3752259
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:47:59
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '1'	System	24 Sep 2020 16:22:07

FDA-CBER-2022-1614-3181415

US3752259
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:47:59
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
Data entry locked.	System	23 Sep 2020 15:13:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 15:13:44

FDA-CBER-2022-1614-3181416

US3752259
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:47:59
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-23T10:31:06', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'f97363cd-1fbc-45c9-9035-005eef3eb35f'	System	23 Sep 2020 15:31:22
User entered 'Yes (Y)'	System	23 Sep 2020 15:31:22

FDA-CBER-2022-1614-3181417

US3752259
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:47:59
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-23T10:31:12', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'f97363cd-1fbc-45c9-9035-005eef3eb35f'	System	23 Sep 2020 15:31:22
User entered '98.8'	System	23 Sep 2020 15:31:22

FDA-CBER-2022-1614-3181418

US3752259
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:47:59
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-23T10:31:16', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'f97363cd-1fbc-45c9-9035-005eef3eb35f'	System	23 Sep 2020 15:31:22
User entered 'No (N)'	System	23 Sep 2020 15:31:22

FDA-CBER-2022-1614-3181419

US3752259
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:47:59
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-23T10:31:19', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'f97363cd-1fbc-45c9-9035-005eef3eb35f'	System	23 Sep 2020 15:31:22
User entered '23 Sep 2020 10:31'	System	23 Sep 2020 15:31:22

FDA-CBER-2022-1614-3181420

US3752259
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:47:59
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '23 Sep 2020 10:30'	System	23 Sep 2020 15:13:44

FDA-CBER-2022-1614-3181421

US3752259
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 09:47:59
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '23 Sep 2020 13:00'	System	23 Sep 2020 15:13:44

FDA-CBER-2022-1614-3181422

US3752259
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:47:59
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
Data entry locked.	System	23 Sep 2020 15:13:44
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 15:13:44

US3752259
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:47:59
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-23T18:06:06', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '944c82ad-00ad-474f-9605-355a39ae69f2'	System	23 Sep 2020 23:06:24
User entered 'Yes (Y)'	System	23 Sep 2020 23:06:24

FDA-CBER-2022-1614-3181424

US3752259
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:47:59
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-23T18:06:13', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '944c82ad-00ad-474f-9605-355a39ae69f2'	System	23 Sep 2020 23:06:24
User entered '96.7'	System	23 Sep 2020 23:06:24

FDA-CBER-2022-1614-3181425

US3752259
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:47:59
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-23T18:06:18', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '944c82ad-00ad-474f-9605-355a39ae69f2'	System	23 Sep 2020 23:06:24
User entered 'No (N)'	System	23 Sep 2020 23:06:24

FDA-CBER-2022-1614-3181426

US3752259
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:47:59
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-23T18:06:23', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '944c82ad-00ad-474f-9605-355a39ae69f2'	System	23 Sep 2020 23:06:24
User entered '23 Sep 2020 18:06'	System	23 Sep 2020 23:06:24

FDA-CBER-2022-1614-3181427

US3752259
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:47:59
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '23 Sep 2020 13:55'	System	23 Sep 2020 15:13:44

FDA-CBER-2022-1614-3181428

US3752259
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 09:47:59
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 15:13:44

FDA-CBER-2022-1614-3181429

US3752259
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:47:59
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
Data entry locked.	System	23 Sep 2020 15:13:44
User entered 'Day 2'	System	23 Sep 2020 15:13:44

FDA-CBER-2022-1614-3181430

US3752259
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:47:59
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-24T18:02:54', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'bfeea1b2-75f7-406e-b1b2-fa9d34a435b7'	System	24 Sep 2020 23:03:16
User entered 'Yes (Y)'	System	24 Sep 2020 23:03:16

FDA-CBER-2022-1614-3181431

US3752259
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:47:59
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-24T18:03:00', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'bfeea1b2-75f7-406e-b1b2-fa9d34a435b7'	System	24 Sep 2020 23:03:16
User entered '99.1'	System	24 Sep 2020 23:03:16

FDA-CBER-2022-1614-3181432

US3752259
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:47:59
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-24T18:03:04', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'bfeea1b2-75f7-406e-b1b2-fa9d34a435b7'	System	24 Sep 2020 23:03:16
User entered 'No (N)'	System	24 Sep 2020 23:03:16

FDA-CBER-2022-1614-3181433

US3752259
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:47:59
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-24T18:03:12', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'bfeea1b2-75f7-406e-b1b2-fa9d34a435b7'	System	24 Sep 2020 23:03:16
User entered '24 Sep 2020 18:03'	System	24 Sep 2020 23:03:16

FDA-CBER-2022-1614-3181434

US3752259
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:47:59
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 15:13:44

FDA-CBER-2022-1614-3181435

US3752259
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 09:47:59
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 15:13:44

FDA-CBER-2022-1614-3181436

US3752259
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:47:59
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
Data entry locked.	System	23 Sep 2020 15:13:44
User entered 'Day 3'	System	23 Sep 2020 15:13:44

FDA-CBER-2022-1614-3181437

US3752259
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:47:59
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-25T18:00:33', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'e961fa7a-126a-4427-ad16-3661ba5ad619'	System	25 Sep 2020 23:00:51
User entered 'Yes (Y)'	System	25 Sep 2020 23:00:51

FDA-CBER-2022-1614-3181438

US3752259
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:47:59
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-25T18:00:38', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'e961fa7a-126a-4427-ad16-3661ba5ad619'	System	25 Sep 2020 23:00:51
User entered '98.4'	System	25 Sep 2020 23:00:51

FDA-CBER-2022-1614-3181439

US3752259
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:47:59
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-25T18:00:43', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'e961fa7a-126a-4427-ad16-3661ba5ad619'	System	25 Sep 2020 23:00:51
User entered 'No (N)'	System	25 Sep 2020 23:00:51

FDA-CBER-2022-1614-3181440

US3752259
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:47:59
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-25T18:00:50', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'e961fa7a-126a-4427-ad16-3661ba5ad619'	System	25 Sep 2020 23:00:51
User entered '25 Sep 2020 18:00'	System	25 Sep 2020 23:00:51

FDA-CBER-2022-1614-3181441

US3752259
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:47:59
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 15:13:44

FDA-CBER-2022-1614-3181442

US3752259
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 09:47:59
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 15:13:44

FDA-CBER-2022-1614-3181443

US3752259
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:47:59
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
Data entry locked.	System	23 Sep 2020 15:13:44
User entered 'Day 4'	System	23 Sep 2020 15:13:44

US3752259
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:47:59
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-26T18:01:45', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'e195886f-db46-4f6e-9d5c-0305100926ff'	System	26 Sep 2020 23:02:00
User entered 'Yes (Y)'	System	26 Sep 2020 23:02:00

FDA-CBER-2022-1614-3181445

US3752259
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:47:59
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-26T18:01:50', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'e195886f-db46-4f6e-9d5c-0305100926ff'	System	26 Sep 2020 23:02:00
User entered '98.3'	System	26 Sep 2020 23:02:00

FDA-CBER-2022-1614-3181446

US3752259
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:47:59
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-26T18:01:54', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'e195886f-db46-4f6e-9d5c-0305100926ff'	System	26 Sep 2020 23:02:00
User entered 'No (N)'	System	26 Sep 2020 23:02:00

FDA-CBER-2022-1614-3181447

US3752259
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:47:59
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-26T18:01:57', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'e195886f-db46-4f6e-9d5c-0305100926ff'	System	26 Sep 2020 23:02:00
User entered '26 Sep 2020 18:01'	System	26 Sep 2020 23:02:00

FDA-CBER-2022-1614-3181448

US3752259
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:47:59
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 15:13:44

FDA-CBER-2022-1614-3181449

US3752259
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 09:47:59
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 15:13:44

FDA-CBER-2022-1614-3181450

US3752259
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:47:59
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
Data entry locked.	System	23 Sep 2020 15:13:44
User entered 'Day 5'	System	23 Sep 2020 15:13:44

US3752259
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:47:59
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-27T18:06:21', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'c9da9df8-ac27-4394-a691-b56dbaa6065a'	System	27 Sep 2020 23:06:40
User entered 'Yes (Y)'	System	27 Sep 2020 23:06:40

FDA-CBER-2022-1614-3181452

US3752259
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:47:59
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-27T18:06:29', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'c9da9df8-ac27-4394-a691-b56dbaa6065a'	System	27 Sep 2020 23:06:40
User entered '97.9'	System	27 Sep 2020 23:06:40

FDA-CBER-2022-1614-3181453

US3752259
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:47:59
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-27T18:06:35', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'c9da9df8-ac27-4394-a691-b56dbaa6065a'	System	27 Sep 2020 23:06:40
User entered 'No (N)'	System	27 Sep 2020 23:06:40

FDA-CBER-2022-1614-3181454

US3752259
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:47:59
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-27T18:06:38', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'c9da9df8-ac27-4394-a691-b56dbaa6065a'	System	27 Sep 2020 23:06:40
User entered '27 Sep 2020 18:06'	System	27 Sep 2020 23:06:40

FDA-CBER-2022-1614-3181455

US3752259
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:47:59
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 15:13:44

FDA-CBER-2022-1614-3181456

US3752259
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 09:47:59
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 15:13:44

FDA-CBER-2022-1614-3181457

US3752259
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:47:59
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
Data entry locked.	System	23 Sep 2020 15:13:44
User entered 'Day 6'	System	23 Sep 2020 15:13:44

US3752259
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:47:59
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-28T18:09:54', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'ec87f801-3e7a-4ae2-b16d-4fa4e1e069ea'	System	28 Sep 2020 23:10:08
User entered 'Yes (Y)'	System	28 Sep 2020 23:10:08

FDA-CBER-2022-1614-3181459

US3752259
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:47:59
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-28T18:09:59', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'ec87f801-3e7a-4ae2-b16d-4fa4e1e069ea'	System	28 Sep 2020 23:10:08
User entered '97.8'	System	28 Sep 2020 23:10:08

FDA-CBER-2022-1614-3181460

US3752259
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:47:59
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-28T18:10:03', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'ec87f801-3e7a-4ae2-b16d-4fa4e1e069ea'	System	28 Sep 2020 23:10:08
User entered 'No (N)'	System	28 Sep 2020 23:10:08

FDA-CBER-2022-1614-3181461

US3752259
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:47:59
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-28T18:10:06', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'ec87f801-3e7a-4ae2-b16d-4fa4e1e069ea'	System	28 Sep 2020 23:10:08
User entered '28 Sep 2020 18:10'	System	28 Sep 2020 23:10:08

FDA-CBER-2022-1614-3181462

US3752259
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:47:59
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 15:13:44

FDA-CBER-2022-1614-3181463

US3752259
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 09:47:59
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 15:13:44

FDA-CBER-2022-1614-3181464

US3752259
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:47:59
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
Data entry locked.	System	23 Sep 2020 15:13:44
User entered 'Day 7'	System	23 Sep 2020 15:13:44

FDA-CBER-2022-1614-3181465

US3752259
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:47:59
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-29T18:03:37', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '9f7a673c-3e60-4f37-b833-9a6da3f112ed'	System	29 Sep 2020 23:04:00
User entered 'Yes (Y)'	System	29 Sep 2020 23:04:00

FDA-CBER-2022-1614-3181466

US3752259
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:47:59
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-29T18:03:45', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '9f7a673c-3e60-4f37-b833-9a6da3f112ed'	System	29 Sep 2020 23:04:00
User entered '97.3'	System	29 Sep 2020 23:04:00

FDA-CBER-2022-1614-3181467

US3752259
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:47:59
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-29T18:03:50', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '9f7a673c-3e60-4f37-b833-9a6da3f112ed'	System	29 Sep 2020 23:04:00
User entered 'No (N)'	System	29 Sep 2020 23:04:00

FDA-CBER-2022-1614-3181468

US3752259
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:47:59
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-29T18:03:58', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '9f7a673c-3e60-4f37-b833-9a6da3f112ed'	System	29 Sep 2020 23:04:00
User entered '29 Sep 2020 18:03'	System	29 Sep 2020 23:04:00

US3752259
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:47:59
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 15:13:44

FDA-CBER-2022-1614-3181470

US3752259
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 09:47:59
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 15:13:44

FDA-CBER-2022-1614-3181471

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:47:59
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
Data entry locked.	System	23 Sep 2020 15:13:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 15:13:44

FDA-CBER-2022-1614-3181472

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:47:59
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 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-23T10:31:26', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '57466faf-6398-4e60-8f3a-cf292f39b488'	System	23 Sep 2020 15:31:48
User entered 'None (1)'	System	23 Sep 2020 15:31:48

FDA-CBER-2022-1614-3181473

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:47:59
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-23T10:31:36', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '57466faf-6398-4e60-8f3a-cf292f39b488'	System	23 Sep 2020 15:31:48
User entered 'No (N)'	System	23 Sep 2020 15:31:48

FDA-CBER-2022-1614-3181474

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:47:59
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-23T10:31:38', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '57466faf-6398-4e60-8f3a-cf292f39b488'	System	23 Sep 2020 15:31:48
User entered 'No (N)'	System	23 Sep 2020 15:31:48

FDA-CBER-2022-1614-3181475

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:47:59
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 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-23T10:31:42', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '57466faf-6398-4e60-8f3a-cf292f39b488'	System	23 Sep 2020 15:31:48
User entered 'None (1)'	System	23 Sep 2020 15:31:48

FDA-CBER-2022-1614-3181476

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:47:59
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-23T10:31:45', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '57466faf-6398-4e60-8f3a-cf292f39b488'	System	23 Sep 2020 15:31:48
User entered '23 Sep 2020 10:31'	System	23 Sep 2020 15:31:48

FDA-CBER-2022-1614-3181477

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:47:59
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '23 Sep 2020 10:30'	System	23 Sep 2020 15:13:44

FDA-CBER-2022-1614-3181478

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 09:47:59
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '23 Sep 2020 13:00'	System	23 Sep 2020 15:13:44

FDA-CBER-2022-1614-3181479

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:47:59
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
Data entry locked.	System	23 Sep 2020 15:13:44
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 15:13:44

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:47:59
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 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-23T18:06:31', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '4490cf85-0794-4630-af9d-a3ec4d8b636d'	System	23 Sep 2020 23:07:04
User entered 'None (1)'	System	23 Sep 2020 23:07:04

FDA-CBER-2022-1614-3181481

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:47:59
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-23T18:06:47', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '4490cf85-0794-4630-af9d-a3ec4d8b636d'	System	23 Sep 2020 23:07:04
User entered 'No (N)'	System	23 Sep 2020 23:07:04

FDA-CBER-2022-1614-3181482

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:47:59
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-23T18:06:51', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '4490cf85-0794-4630-af9d-a3ec4d8b636d'	System	23 Sep 2020 23:07:04
User entered 'No (N)'	System	23 Sep 2020 23:07:04

FDA-CBER-2022-1614-3181483

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:47:59
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 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-23T18:06:56', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '4490cf85-0794-4630-af9d-a3ec4d8b636d'	System	23 Sep 2020 23:07:04
User entered 'None (1)'	System	23 Sep 2020 23:07:04

FDA-CBER-2022-1614-3181484

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:47:59
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-23T18:07:01', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '4490cf85-0794-4630-af9d-a3ec4d8b636d'	System	23 Sep 2020 23:07:04
User entered '23 Sep 2020 18:07'	System	23 Sep 2020 23:07:04

FDA-CBER-2022-1614-3181485

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:47:59
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '23 Sep 2020 13:55'	System	23 Sep 2020 15:13:44

FDA-CBER-2022-1614-3181486

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 09:47:59
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 15:13:44

FDA-CBER-2022-1614-3181487

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:47:59
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
Data entry locked.	System	23 Sep 2020 15:13:44
User entered 'Day 2'	System	23 Sep 2020 15:13:44

FDA-CBER-2022-1614-3181488

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:47:59
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 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-24T18:03:17', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '0149da34-6c76-42cf-8f4b-556eca693bbf'	System	24 Sep 2020 23:03:35
User entered 'None (1)'	System	24 Sep 2020 23:03:35

FDA-CBER-2022-1614-3181489

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:47:59
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-24T18:03:20', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '0149da34-6c76-42cf-8f4b-556eca693bbf'	System	24 Sep 2020 23:03:35
User entered 'No (N)'	System	24 Sep 2020 23:03:35

FDA-CBER-2022-1614-3181490

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:47:59
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-24T18:03:23', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '0149da34-6c76-42cf-8f4b-556eca693bbf'	System	24 Sep 2020 23:03:35
User entered 'No (N)'	System	24 Sep 2020 23:03:35

FDA-CBER-2022-1614-3181491

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:47:59
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 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-24T18:03:27', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '0149da34-6c76-42cf-8f4b-556eca693bbf'	System	24 Sep 2020 23:03:35
User entered 'None (1)'	System	24 Sep 2020 23:03:35

FDA-CBER-2022-1614-3181492

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:47:59
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-24T18:03:30', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '0149da34-6c76-42cf-8f4b-556eca693bbf'	System	24 Sep 2020 23:03:35
User entered '24 Sep 2020 18:03'	System	24 Sep 2020 23:03:35

FDA-CBER-2022-1614-3181493

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:47:59
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 15:13:44

FDA-CBER-2022-1614-3181494

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 09:47:59
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 15:13:44

FDA-CBER-2022-1614-3181495

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:47:59
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
Data entry locked.	System	23 Sep 2020 15:13:44
User entered 'Day 3'	System	23 Sep 2020 15:13:44

FDA-CBER-2022-1614-3181496

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:47:59
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 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-25T18:01:18', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '344079b9-1051-41a0-ae85-3ba8c6dd6d08'	System	25 Sep 2020 23:01:37
User entered 'None (1)'	System	25 Sep 2020 23:01:37

FDA-CBER-2022-1614-3181497

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:47:59
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-25T18:01:21', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '344079b9-1051-41a0-ae85-3ba8c6dd6d08'	System	25 Sep 2020 23:01:37
User entered 'No (N)'	System	25 Sep 2020 23:01:37

FDA-CBER-2022-1614-3181498

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:47:59
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-25T18:01:24', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '344079b9-1051-41a0-ae85-3ba8c6dd6d08'	System	25 Sep 2020 23:01:37
User entered 'No (N)'	System	25 Sep 2020 23:01:37

FDA-CBER-2022-1614-3181499

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:47:59
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 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-25T18:01:29', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '344079b9-1051-41a0-ae85-3ba8c6dd6d08'	System	25 Sep 2020 23:01:37
User entered 'None (1)'	System	25 Sep 2020 23:01:37

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:47:59
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-25T18:01:31', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '344079b9-1051-41a0-ae85-3ba8c6dd6d08'	System	25 Sep 2020 23:01:37
User entered '25 Sep 2020 18:01'	System	25 Sep 2020 23:01:37

FDA-CBER-2022-1614-3181501

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:47:59
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 15:13:44

FDA-CBER-2022-1614-3181502

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 09:47:59
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 15:13:44

FDA-CBER-2022-1614-3181503

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:47:59
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
Data entry locked.	System	23 Sep 2020 15:13:44
User entered 'Day 4'	System	23 Sep 2020 15:13:44

FDA-CBER-2022-1614-3181504

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:47:59
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 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-26T18:02:06', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '7013cd17-3379-47b7-bf23-01d1e7b607ff'	System	26 Sep 2020 23:02:23
User entered 'None (1)'	System	26 Sep 2020 23:02:23

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:47:59
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-26T18:02:09', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '7013cd17-3379-47b7-bf23-01d1e7b607ff'	System	26 Sep 2020 23:02:23
User entered 'No (N)'	System	26 Sep 2020 23:02:23

FDA-CBER-2022-1614-3181506

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:47:59
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-26T18:02:12', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '7013cd17-3379-47b7-bf23-01d1e7b607ff'	System	26 Sep 2020 23:02:23
User entered 'No (N)'	System	26 Sep 2020 23:02:23

FDA-CBER-2022-1614-3181507

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:47:59
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 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-26T18:02:15', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '7013cd17-3379-47b7-bf23-01d1e7b607ff'	System	26 Sep 2020 23:02:23
User entered 'None (1)'	System	26 Sep 2020 23:02:23

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:47:59
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-26T18:02:22', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '7013cd17-3379-47b7-bf23-01d1e7b607ff'	System	26 Sep 2020 23:02:23
User entered '26 Sep 2020 18:02'	System	26 Sep 2020 23:02:23

FDA-CBER-2022-1614-3181509

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:47:59
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 15:13:44

FDA-CBER-2022-1614-3181510

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 09:47:59
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 15:13:44

FDA-CBER-2022-1614-3181511

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:47:59
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
Data entry locked.	System	23 Sep 2020 15:13:44
User entered 'Day 5'	System	23 Sep 2020 15:13:44

FDA-CBER-2022-1614-3181512

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:47:59
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 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-27T18:07:00', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '0e29e3fd-3090-4bbe-9b7c-70cf0f67567a'	System	27 Sep 2020 23:07:18
User entered 'None (1)'	System	27 Sep 2020 23:07:18

FDA-CBER-2022-1614-3181513

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:47:59
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-27T18:07:04', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '0e29e3fd-3090-4bbe-9b7c-70cf0f67567a'	System	27 Sep 2020 23:07:18
User entered 'No (N)'	System	27 Sep 2020 23:07:18

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:47:59
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-27T18:07:07', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '0e29e3fd-3090-4bbe-9b7c-70cf0f67567a'	System	27 Sep 2020 23:07:18
User entered 'No (N)'	System	27 Sep 2020 23:07:18

FDA-CBER-2022-1614-3181515

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:47:59
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 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-27T18:07:12', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '0e29e3fd-3090-4bbe-9b7c-70cf0f67567a'	System	27 Sep 2020 23:07:18
User entered 'None (1)'	System	27 Sep 2020 23:07:18

FDA-CBER-2022-1614-3181516

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:47:59
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-27T18:07:16', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '0e29e3fd-3090-4bbe-9b7c-70cf0f67567a'	System	27 Sep 2020 23:07:18
User entered '27 Sep 2020 18:07'	System	27 Sep 2020 23:07:18

FDA-CBER-2022-1614-3181517

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:47:59
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 15:13:44

FDA-CBER-2022-1614-3181518

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 09:47:59
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 15:13:44

FDA-CBER-2022-1614-3181519

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:47:59
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
Data entry locked.	System	23 Sep 2020 15:13:44
User entered 'Day 6'	System	23 Sep 2020 15:13:44

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:47:59
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 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-28T18:10:33', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '963ddc8a-6aea-4828-b8ec-45bd7a61f051'	System	28 Sep 2020 23:10:52
User entered 'None (1)'	System	28 Sep 2020 23:10:52

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:47:59
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-28T18:10:36', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '963ddc8a-6aea-4828-b8ec-45bd7a61f051'	System	28 Sep 2020 23:10:52
User entered 'No (N)'	System	28 Sep 2020 23:10:52

FDA-CBER-2022-1614-3181522

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:47:59
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-28T18:10:40', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '963ddc8a-6aea-4828-b8ec-45bd7a61f051'	System	28 Sep 2020 23:10:52
User entered 'No (N)'	System	28 Sep 2020 23:10:52

FDA-CBER-2022-1614-3181523

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:47:59
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 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-28T18:10:43', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '963ddc8a-6aea-4828-b8ec-45bd7a61f051'	System	28 Sep 2020 23:10:52
User entered 'None (1)'	System	28 Sep 2020 23:10:52

FDA-CBER-2022-1614-3181524

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:47:59
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-28T18:10:46', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '963ddc8a-6aea-4828-b8ec-45bd7a61f051'	System	28 Sep 2020 23:10:52
User entered '28 Sep 2020 18:10'	System	28 Sep 2020 23:10:52

FDA-CBER-2022-1614-3181525

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:47:59
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 15:13:44

FDA-CBER-2022-1614-3181526

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 09:47:59
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 15:13:44

FDA-CBER-2022-1614-3181527

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:47:59
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
Data entry locked.	System	23 Sep 2020 15:13:44
User entered 'Day 7'	System	23 Sep 2020 15:13:44

FDA-CBER-2022-1614-3181528

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:47:59
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 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-29T18:04:02', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '2903c396-33ee-45ca-8063-b9fdccba3a6c'	System	29 Sep 2020 23:04:21
User entered 'None (1)'	System	29 Sep 2020 23:04:21

FDA-CBER-2022-1614-3181529

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:47:59
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-29T18:04:05', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '2903c396-33ee-45ca-8063-b9fdccba3a6c'	System	29 Sep 2020 23:04:21
User entered 'No (N)'	System	29 Sep 2020 23:04:21

FDA-CBER-2022-1614-3181530

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:47:59
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-29T18:04:08', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '2903c396-33ee-45ca-8063-b9fdccba3a6c'	System	29 Sep 2020 23:04:21
User entered 'No (N)'	System	29 Sep 2020 23:04:21

FDA-CBER-2022-1614-3181531

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:47:59
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 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-29T18:04:12', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '2903c396-33ee-45ca-8063-b9fdccba3a6c'	System	29 Sep 2020 23:04:21
User entered 'None (1)'	System	29 Sep 2020 23:04:21

FDA-CBER-2022-1614-3181532

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:47:59
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-29T18:04:18', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '2903c396-33ee-45ca-8063-b9fdccba3a6c'	System	29 Sep 2020 23:04:21
User entered '29 Sep 2020 18:04'	System	29 Sep 2020 23:04:21

FDA-CBER-2022-1614-3181533

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:47:59
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 15:13:44

FDA-CBER-2022-1614-3181534

US3752259
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 09:47:59
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 15:13:44

FDA-CBER-2022-1614-3181535

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:47:59
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
Data entry locked.	System	23 Sep 2020 15:13:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 15:13:44

FDA-CBER-2022-1614-3181536

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:47:59
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-23T10:31:49', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '371df49e-96f2-44ea-af3e-906e00ef2d41'	System	23 Sep 2020 15:32:13
User entered 'None (0)'	System	23 Sep 2020 15:32:13

FDA-CBER-2022-1614-3181537

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:47:59
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-23T10:31:54', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '371df49e-96f2-44ea-af3e-906e00ef2d41'	System	23 Sep 2020 15:32:13
User entered 'None (0)'	System	23 Sep 2020 15:32:13

FDA-CBER-2022-1614-3181538

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:47:59
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-23T10:31:56', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '371df49e-96f2-44ea-af3e-906e00ef2d41'	System	23 Sep 2020 15:32:13
User entered 'None (0)'	System	23 Sep 2020 15:32:13

FDA-CBER-2022-1614-3181539

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:47:59
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-23T10:31:59', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '371df49e-96f2-44ea-af3e-906e00ef2d41'	System	23 Sep 2020 15:32:13
User entered 'None (0)'	System	23 Sep 2020 15:32:13

FDA-CBER-2022-1614-3181540

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:47:59
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-23T10:32:01', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '371df49e-96f2-44ea-af3e-906e00ef2d41'	System	23 Sep 2020 15:32:13
User entered 'None (0)'	System	23 Sep 2020 15:32:13

FDA-CBER-2022-1614-3181541

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:47:59
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-23T10:32:03', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '371df49e-96f2-44ea-af3e-906e00ef2d41'	System	23 Sep 2020 15:32:13
User entered 'None (0)'	System	23 Sep 2020 15:32:13

FDA-CBER-2022-1614-3181542

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:47:59
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 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-23T10:32:07', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '371df49e-96f2-44ea-af3e-906e00ef2d41'	System	23 Sep 2020 15:32:13
User entered 'No (N)'	System	23 Sep 2020 15:32:13

FDA-CBER-2022-1614-3181543

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:47:59
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-23T10:32:10', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '371df49e-96f2-44ea-af3e-906e00ef2d41'	System	23 Sep 2020 15:32:13
User entered '23 Sep 2020 10:32'	System	23 Sep 2020 15:32:13

FDA-CBER-2022-1614-3181544

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:47:59
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '23 Sep 2020 10:30'	System	23 Sep 2020 15:13:44

FDA-CBER-2022-1614-3181545

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 09:47:59
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '23 Sep 2020 13:00'	System	23 Sep 2020 15:13:44

FDA-CBER-2022-1614-3181546

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:47:59
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
Data entry locked.	System	23 Sep 2020 15:13:44
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 15:13:44

FDA-CBER-2022-1614-3181547

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:47:59
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-23T18:07:08', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '1283d9a8-7d3a-4fac-b429-748af4e71621'	System	23 Sep 2020 23:07:35
User entered 'None (0)'	System	23 Sep 2020 23:07:35

FDA-CBER-2022-1614-3181548

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:47:59
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-23T18:07:11', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '1283d9a8-7d3a-4fac-b429-748af4e71621'	System	23 Sep 2020 23:07:35
User entered 'None (0)'	System	23 Sep 2020 23:07:35

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:47:59
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-23T18:07:14', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '1283d9a8-7d3a-4fac-b429-748af4e71621'	System	23 Sep 2020 23:07:35
User entered 'None (0)'	System	23 Sep 2020 23:07:35

FDA-CBER-2022-1614-3181550

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:47:59
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-23T18:07:18', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '1283d9a8-7d3a-4fac-b429-748af4e71621'	System	23 Sep 2020 23:07:35
User entered 'None (0)'	System	23 Sep 2020 23:07:35

FDA-CBER-2022-1614-3181551

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:47:59
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-23T18:07:21', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '1283d9a8-7d3a-4fac-b429-748af4e71621'	System	23 Sep 2020 23:07:35
User entered 'None (0)'	System	23 Sep 2020 23:07:35

FDA-CBER-2022-1614-3181552

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:47:59
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-23T18:07:24', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '1283d9a8-7d3a-4fac-b429-748af4e71621'	System	23 Sep 2020 23:07:35
User entered 'None (0)'	System	23 Sep 2020 23:07:35

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:47:59
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 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-23T18:07:28', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '1283d9a8-7d3a-4fac-b429-748af4e71621'	System	23 Sep 2020 23:07:35
User entered 'No (N)'	System	23 Sep 2020 23:07:35

FDA-CBER-2022-1614-3181554

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:47:59
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-23T18:07:33', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '1283d9a8-7d3a-4fac-b429-748af4e71621'	System	23 Sep 2020 23:07:35
User entered '23 Sep 2020 18:07'	System	23 Sep 2020 23:07:35

FDA-CBER-2022-1614-3181555

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:47:59
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '23 Sep 2020 13:55'	System	23 Sep 2020 15:13:44

FDA-CBER-2022-1614-3181556

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 09:47:59
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 15:13:44

FDA-CBER-2022-1614-3181557

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:47:59
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
Data entry locked.	System	23 Sep 2020 15:13:44
User entered 'Day 2'	System	23 Sep 2020 15:13:44

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:47:59
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-24T18:03:37', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'ad7e2e1b-fac1-4fbb-9d07-d34fdc72d760'	System	24 Sep 2020 23:03:58
User entered 'None (0)'	System	24 Sep 2020 23:03:58

FDA-CBER-2022-1614-3181559

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:47:59
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-24T18:03:39', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'ad7e2e1b-fac1-4fbb-9d07-d34fdc72d760'	System	24 Sep 2020 23:03:58
User entered 'None (0)'	System	24 Sep 2020 23:03:58

FDA-CBER-2022-1614-3181560

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:47:59
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-24T18:03:41', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'ad7e2e1b-fac1-4fbb-9d07-d34fdc72d760'	System	24 Sep 2020 23:03:58
User entered 'None (0)'	System	24 Sep 2020 23:03:58

FDA-CBER-2022-1614-3181561

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:47:59
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-24T18:03:43', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'ad7e2e1b-fac1-4fbb-9d07-d34fdc72d760'	System	24 Sep 2020 23:03:58
User entered 'None (0)'	System	24 Sep 2020 23:03:58

FDA-CBER-2022-1614-3181562

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:47:59
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-24T18:03:45', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'ad7e2e1b-fac1-4fbb-9d07-d34fdc72d760'	System	24 Sep 2020 23:03:58
User entered 'None (0)'	System	24 Sep 2020 23:03:58

FDA-CBER-2022-1614-3181563

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:47:59
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-24T18:03:47', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'ad7e2e1b-fac1-4fbb-9d07-d34fdc72d760'	System	24 Sep 2020 23:03:58
User entered 'None (0)'	System	24 Sep 2020 23:03:58

FDA-CBER-2022-1614-3181564

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:47:59
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 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-24T18:03:50', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'ad7e2e1b-fac1-4fbb-9d07-d34fdc72d760'	System	24 Sep 2020 23:03:58
User entered 'No (N)'	System	24 Sep 2020 23:03:58

FDA-CBER-2022-1614-3181565

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:47:59
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-24T18:03:54', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'ad7e2e1b-fac1-4fbb-9d07-d34fdc72d760'	System	24 Sep 2020 23:03:58
User entered '24 Sep 2020 18:03'	System	24 Sep 2020 23:03:58

FDA-CBER-2022-1614-3181566

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:47:59
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 15:13:44

FDA-CBER-2022-1614-3181567

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 09:47:59
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 15:13:44

FDA-CBER-2022-1614-3181568

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:47:59
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
Data entry locked.	System	23 Sep 2020 15:13:44
User entered 'Day 3'	System	23 Sep 2020 15:13:44

FDA-CBER-2022-1614-3181569

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:47:59
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-25T18:01:36', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'f80070f3-775b-4d32-8de6-865ea5056c9b'	System	25 Sep 2020 23:02:27
User entered 'None (0)'	System	25 Sep 2020 23:02:27

FDA-CBER-2022-1614-3181570

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:47:59
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-25T18:01:39', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'f80070f3-775b-4d32-8de6-865ea5056c9b'	System	25 Sep 2020 23:02:27
User entered 'None (0)'	System	25 Sep 2020 23:02:27

FDA-CBER-2022-1614-3181571

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:47:59
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-25T18:02:02', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'f80070f3-775b-4d32-8de6-865ea5056c9b'	System	25 Sep 2020 23:02:27
User entered 'No interference with activity (1)'	System	25 Sep 2020 23:02:27

FDA-CBER-2022-1614-3181572

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:47:59
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-25T18:02:06', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'f80070f3-775b-4d32-8de6-865ea5056c9b'	System	25 Sep 2020 23:02:27
User entered 'None (0)'	System	25 Sep 2020 23:02:27

FDA-CBER-2022-1614-3181573

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:47:59
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-25T18:02:09', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'f80070f3-775b-4d32-8de6-865ea5056c9b'	System	25 Sep 2020 23:02:27
User entered 'None (0)'	System	25 Sep 2020 23:02:27

FDA-CBER-2022-1614-3181574

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:47:59
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-25T18:02:13', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'f80070f3-775b-4d32-8de6-865ea5056c9b'	System	25 Sep 2020 23:02:27
User entered 'None (0)'	System	25 Sep 2020 23:02:27

FDA-CBER-2022-1614-3181575

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:47:59
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 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-25T18:02:17', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'f80070f3-775b-4d32-8de6-865ea5056c9b'	System	25 Sep 2020 23:02:27
User entered 'No (N)'	System	25 Sep 2020 23:02:27

FDA-CBER-2022-1614-3181576

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:47:59
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-25T18:02:24', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'f80070f3-775b-4d32-8de6-865ea5056c9b'	System	25 Sep 2020 23:02:27
User entered '25 Sep 2020 18:02'	System	25 Sep 2020 23:02:27

FDA-CBER-2022-1614-3181577

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:47:59
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 15:13:44

FDA-CBER-2022-1614-3181578

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 09:47:59
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 15:13:44

FDA-CBER-2022-1614-3181579

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:47:59
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
Data entry locked.	System	23 Sep 2020 15:13:44
User entered 'Day 4'	System	23 Sep 2020 15:13:44

FDA-CBER-2022-1614-3181580

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:47:59
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-26T18:02:26', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '03b1e597-5b6d-4a66-b908-51116518c717'	System	26 Sep 2020 23:02:52
User entered 'None (0)'	System	26 Sep 2020 23:02:52

FDA-CBER-2022-1614-3181581

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:47:59
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-26T18:02:30', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '03b1e597-5b6d-4a66-b908-51116518c717'	System	26 Sep 2020 23:02:52
User entered 'None (0)'	System	26 Sep 2020 23:02:52

FDA-CBER-2022-1614-3181582

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:47:59
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-26T18:02:33', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '03b1e597-5b6d-4a66-b908-51116518c717'	System	26 Sep 2020 23:02:52
User entered 'None (0)'	System	26 Sep 2020 23:02:52

FDA-CBER-2022-1614-3181583

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:47:59
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-26T18:02:35', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '03b1e597-5b6d-4a66-b908-51116518c717'	System	26 Sep 2020 23:02:52
User entered 'None (0)'	System	26 Sep 2020 23:02:52

FDA-CBER-2022-1614-3181584

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:47:59
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-26T18:02:38', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '03b1e597-5b6d-4a66-b908-51116518c717'	System	26 Sep 2020 23:02:52
User entered 'None (0)'	System	26 Sep 2020 23:02:52

FDA-CBER-2022-1614-3181585

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:47:59
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-26T18:02:40', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '03b1e597-5b6d-4a66-b908-51116518c717'	System	26 Sep 2020 23:02:52
User entered 'None (0)'	System	26 Sep 2020 23:02:52

FDA-CBER-2022-1614-3181586

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:47:59
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 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-26T18:02:43', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '03b1e597-5b6d-4a66-b908-51116518c717'	System	26 Sep 2020 23:02:52
User entered 'No (N)'	System	26 Sep 2020 23:02:52

FDA-CBER-2022-1614-3181587

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:47:59
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-26T18:02:49', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '03b1e597-5b6d-4a66-b908-51116518c717'	System	26 Sep 2020 23:02:52
User entered '26 Sep 2020 18:02'	System	26 Sep 2020 23:02:52

FDA-CBER-2022-1614-3181588

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:47:59
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 15:13:44

FDA-CBER-2022-1614-3181589

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 09:47:59
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 15:13:44

FDA-CBER-2022-1614-3181590

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:47:59
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
Data entry locked.	System	23 Sep 2020 15:13:44
User entered 'Day 5'	System	23 Sep 2020 15:13:44

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:47:59
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-27T18:07:25', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'a6f72885-1c83-4ea4-925c-cbebde99afb0'	System	27 Sep 2020 23:07:53
User entered 'None (0)'	System	27 Sep 2020 23:07:53

FDA-CBER-2022-1614-3181592

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:47:59
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-27T18:07:28', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'a6f72885-1c83-4ea4-925c-cbebde99afb0'	System	27 Sep 2020 23:07:53
User entered 'None (0)'	System	27 Sep 2020 23:07:53

FDA-CBER-2022-1614-3181593

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:47:59
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-27T18:07:31', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'a6f72885-1c83-4ea4-925c-cbebde99afb0'	System	27 Sep 2020 23:07:53
User entered 'None (0)'	System	27 Sep 2020 23:07:53

FDA-CBER-2022-1614-3181594

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:47:59
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-27T18:07:35', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'a6f72885-1c83-4ea4-925c-cbebde99afb0'	System	27 Sep 2020 23:07:53
User entered 'None (0)'	System	27 Sep 2020 23:07:53

FDA-CBER-2022-1614-3181595

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:47:59
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-27T18:07:38', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'a6f72885-1c83-4ea4-925c-cbebde99afb0'	System	27 Sep 2020 23:07:53
User entered 'None (0)'	System	27 Sep 2020 23:07:53

FDA-CBER-2022-1614-3181596

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:47:59
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-27T18:07:42', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'a6f72885-1c83-4ea4-925c-cbebde99afb0'	System	27 Sep 2020 23:07:53
User entered 'None (0)'	System	27 Sep 2020 23:07:53

FDA-CBER-2022-1614-3181597

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:47:59
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 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-27T18:07:47', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'a6f72885-1c83-4ea4-925c-cbebde99afb0'	System	27 Sep 2020 23:07:53
User entered 'No (N)'	System	27 Sep 2020 23:07:53

FDA-CBER-2022-1614-3181598

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:47:59
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-27T18:07:52', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'a6f72885-1c83-4ea4-925c-cbebde99afb0'	System	27 Sep 2020 23:07:53
User entered '27 Sep 2020 18:07'	System	27 Sep 2020 23:07:53

FDA-CBER-2022-1614-3181599

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:47:59
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 15:13:44

FDA-CBER-2022-1614-3181600

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 09:47:59
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 15:13:44

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:47:59
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
Data entry locked.	System	23 Sep 2020 15:13:44
User entered 'Day 6'	System	23 Sep 2020 15:13:44

FDA-CBER-2022-1614-3181602

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:47:59
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-28T18:10:51', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '2c0de615-aeec-4cd7-aa53-44a5a16274c9'	System	28 Sep 2020 23:11:14
User entered 'None (0)'	System	28 Sep 2020 23:11:14

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:47:59
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-28T18:10:53', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '2c0de615-aeec-4cd7-aa53-44a5a16274c9'	System	28 Sep 2020 23:11:14
User entered 'None (0)'	System	28 Sep 2020 23:11:14

FDA-CBER-2022-1614-3181604

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:47:59
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-28T18:10:56', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '2c0de615-aeec-4cd7-aa53-44a5a16274c9'	System	28 Sep 2020 23:11:14
User entered 'None (0)'	System	28 Sep 2020 23:11:14

FDA-CBER-2022-1614-3181605

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:47:59
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-28T18:10:59', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '2c0de615-aeec-4cd7-aa53-44a5a16274c9'	System	28 Sep 2020 23:11:14
User entered 'None (0)'	System	28 Sep 2020 23:11:14

FDA-CBER-2022-1614-3181606

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:47:59
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-28T18:11:02', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '2c0de615-aeec-4cd7-aa53-44a5a16274c9'	System	28 Sep 2020 23:11:14
User entered 'None (0)'	System	28 Sep 2020 23:11:14

FDA-CBER-2022-1614-3181607

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:47:59
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-28T18:11:04', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '2c0de615-aeec-4cd7-aa53-44a5a16274c9'	System	28 Sep 2020 23:11:14
User entered 'None (0)'	System	28 Sep 2020 23:11:14

FDA-CBER-2022-1614-3181608

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:47:59
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 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-28T18:11:08', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '2c0de615-aeec-4cd7-aa53-44a5a16274c9'	System	28 Sep 2020 23:11:14
User entered 'No (N)'	System	28 Sep 2020 23:11:14

FDA-CBER-2022-1614-3181609

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:47:59
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-28T18:11:11', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '2c0de615-aeec-4cd7-aa53-44a5a16274c9'	System	28 Sep 2020 23:11:14
User entered '28 Sep 2020 18:11'	System	28 Sep 2020 23:11:14

FDA-CBER-2022-1614-3181610

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:47:59
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 15:13:44

FDA-CBER-2022-1614-3181611

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 09:47:59
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 15:13:44

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:47:59
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
Data entry locked.	System	23 Sep 2020 15:13:44
User entered 'Day 7'	System	23 Sep 2020 15:13:44

FDA-CBER-2022-1614-3181613

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:47:59
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-29T18:04:22', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'a5663522-426c-4d7d-becf-2a0d84bd4201'	System	29 Sep 2020 23:04:53
User entered 'None (0)'	System	29 Sep 2020 23:04:53

FDA-CBER-2022-1614-3181614

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:47:59
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-29T18:04:25', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'a5663522-426c-4d7d-becf-2a0d84bd4201'	System	29 Sep 2020 23:04:53
User entered 'None (0)'	System	29 Sep 2020 23:04:53

FDA-CBER-2022-1614-3181615

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:47:59
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-29T18:04:29', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'a5663522-426c-4d7d-becf-2a0d84bd4201'	System	29 Sep 2020 23:04:53
User entered 'None (0)'	System	29 Sep 2020 23:04:53

FDA-CBER-2022-1614-3181616

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:47:59
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-29T18:04:31', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'a5663522-426c-4d7d-becf-2a0d84bd4201'	System	29 Sep 2020 23:04:53
User entered 'None (0)'	System	29 Sep 2020 23:04:53

FDA-CBER-2022-1614-3181617

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:47:59
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-29T18:04:35', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'a5663522-426c-4d7d-becf-2a0d84bd4201'	System	29 Sep 2020 23:04:53
User entered 'None (0)'	System	29 Sep 2020 23:04:53

FDA-CBER-2022-1614-3181618

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:47:59
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-29T18:04:40', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'a5663522-426c-4d7d-becf-2a0d84bd4201'	System	29 Sep 2020 23:04:53
User entered 'None (0)'	System	29 Sep 2020 23:04:53

FDA-CBER-2022-1614-3181619

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:47:59
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 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-29T18:04:45', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'a5663522-426c-4d7d-becf-2a0d84bd4201'	System	29 Sep 2020 23:04:53
User entered 'No (N)'	System	29 Sep 2020 23:04:53

FDA-CBER-2022-1614-3181620

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:47:59
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-09-29T18:04:50', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'a5663522-426c-4d7d-becf-2a0d84bd4201'	System	29 Sep 2020 23:04:53
User entered '29 Sep 2020 18:04'	System	29 Sep 2020 23:04:53

FDA-CBER-2022-1614-3181621

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:47:59
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 15:13:44

FDA-CBER-2022-1614-3181622

US3752259
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 09:47:59
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 15:13:44

FDA-CBER-2022-1614-3181623

US3752259
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:47:59
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:47:36
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 20:08:35

FDA-CBER-2022-1614-3181624

US3752259
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:47:59
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:47:38
User entered '30 Sep 2020'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 20:08:35

FDA-CBER-2022-1614-3181625

US3752259
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:47:59
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:47:39
User entered 'Contact Made (CONTACT MADE)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 20:08:35

US3752259
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:47:59
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:47:41
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 20:08:35

FDA-CBER-2022-1614-3181627

US3752259
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:47:59
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:47:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 20:06:19

US3752259
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:47:59
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '1'	System	07 Oct 2020 20:06:19

FDA-CBER-2022-1614-3181629

US3752259
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:47:59
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:48:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 20:06:36

FDA-CBER-2022-1614-3181630

US3752259
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:47:59
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:48:17
User entered '7 Oct 2020'	(b) (4), (b) (6)	07 Oct 2020 20:06:36

US3752259
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:47:59
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:48:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	07 Oct 2020 20:06:36

US3752259
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:47:59
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 15:48:20
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 20:06:36

US3752259
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:47:59
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:48:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 17:03:04

FDA-CBER-2022-1614-3181634

US3752259
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:47:59
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '1'	System	14 Oct 2020 17:03:04

FDA-CBER-2022-1614-3181635

US3752259
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:47:59
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:49:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 17:03:24

US3752259
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:47:59
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:49:26
User entered '14 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 17:03:24

FDA-CBER-2022-1614-3181637

US3752259
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:47:59
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:49:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	14 Oct 2020 17:03:24

FDA-CBER-2022-1614-3181638

US3752259
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:47:59
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 15:49:30
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 17:03:24

FDA-CBER-2022-1614-3181639

US3752259
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:47:59
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:49:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Oct 2020 18:47:47

US3752259
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:47:59
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '1'	System	29 Oct 2020 18:47:47

FDA-CBER-2022-1614-3181641

US3752259
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:47:59
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:56:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Oct 2020 18:48:03

FDA-CBER-2022-1614-3181642

US3752259
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:47:59
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:56:29
User entered '28 Oct 2020'	(b) (4), (b) (6)	29 Oct 2020 18:48:03

FDA-CBER-2022-1614-3181643

US3752259
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:47:59
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 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:56:31
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	29 Oct 2020 18:48:03

US3752259
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:47:59
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered 'VISIT3'	System	29 Oct 2020 18:48:03

FDA-CBER-2022-1614-3181645

US3752259
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:47:59
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:56:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Oct 2020 18:48:37

FDA-CBER-2022-1614-3181646

US3752259
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:47:59
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 15:56:48
User entered '28 Oct 2020'	(b) (4), (b) (6)	29 Oct 2020 18:48:37

FDA-CBER-2022-1614-3181647

US3752259
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:47:59
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:56:50
User entered '10:10'	(b) (4), (b) (6)	29 Oct 2020 18:48:37

FDA-CBER-2022-1614-3181648

US3752259
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:47:59
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '28 Oct 2020 10:10'	System	29 Oct 2020 18:48:37

FDA-CBER-2022-1614-3181649

US3752259
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:47:59
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:56:52
User entered '97.5' F	(b) (4), (b) (6)	29 Oct 2020 18:48:37

US3752259
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:47:59
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:56:55
User entered 'Oral (Oral)'	(b) (4), (b) (6)	29 Oct 2020 18:48:37

US3752259
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:47:59
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:56:57
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 18:48:37

FDA-CBER-2022-1614-3181652

US3752259
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:47:59
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:57:00
User entered '66'	(b) (4), (b) (6)	29 Oct 2020 18:48:37

FDA-CBER-2022-1614-3181653

US3752259
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:47:59
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered 'bpm'	System	29 Oct 2020 18:48:37

FDA-CBER-2022-1614-3181654

US3752259
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:47:59
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:57:02
User entered '18'	(b) (4), (b) (6)	29 Oct 2020 18:48:37

FDA-CBER-2022-1614-3181655

US3752259
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:47:59
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered 'breaths/min'	System	29 Oct 2020 18:48:37

FDA-CBER-2022-1614-3181656

US3752259
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:47:59
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:57:06
User entered '136'	(b) (4), (b) (6)	29 Oct 2020 18:48:37

FDA-CBER-2022-1614-3181657

US3752259
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:47:59
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered 'mmHg'	System	29 Oct 2020 18:48:37

FDA-CBER-2022-1614-3181658

US3752259
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:47:59
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:57:07
User entered '88'	(b) (4), (b) (6)	29 Oct 2020 18:48:37

FDA-CBER-2022-1614-3181659

US3752259
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:47:59
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered 'mmHg'	System	29 Oct 2020 18:48:37

FDA-CBER-2022-1614-3181660

US3752259
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:47:59
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04

FDA-CBER-2022-1614-3181661

US3752259
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 09:47:59
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04

FDA-CBER-2022-1614-3181662

US3752259
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:47:59
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:57:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Oct 2020 18:48:46

US3752259
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 09:47:59
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:57:26
User entered '28 Oct 2020'	(b) (4), (b) (6)	29 Oct 2020 18:48:46

FDA-CBER-2022-1614-3181664

US3752259
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:47:59
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:57:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Oct 2020 18:49:09

US3752259
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:47:59
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 15:57:46
User entered '28 Oct 2020'	(b) (4), (b) (6)	29 Oct 2020 18:49:09

FDA-CBER-2022-1614-3181666

US3752259
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:47:59
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:57:48
User entered '10:15'	(b) (4), (b) (6)	29 Oct 2020 18:49:09

FDA-CBER-2022-1614-3181667

US3752259
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:47:59
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '28 Oct 2020 10:15'	System	29 Oct 2020 18:49:09

FDA-CBER-2022-1614-3181668

US3752259
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:47:59
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:57:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Oct 2020 18:49:13

FDA-CBER-2022-1614-3181669

US3752259
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:47:59
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '1'	System	29 Oct 2020 18:49:13

FDA-CBER-2022-1614-3181670

US3752259
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
Data entry locked.	System	26 Aug 2020 15:44:50
User entered 'Day 64'	System	26 Aug 2020 15:44:50

US3752259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:47:59

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-10-26T16:42:58', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '2e69da6e-269a-4e81-951e-16412756cf87'	System	26 Oct 2020 21:43:12
User entered 'No (N)'	System	26 Oct 2020 21:43:12

US3752259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:47:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-10-26T16:43:05', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '2e69da6e-269a-4e81-951e-16412756cf87'	System	26 Oct 2020 21:43:12
User entered 'No (N)'	System	26 Oct 2020 21:43:12

US3752259
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-10-26T16:43:09', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '2e69da6e-269a-4e81-951e-16412756cf87'	System	26 Oct 2020 21:43:12
User entered '26 Oct 2020 16:43:09'	System	26 Oct 2020 21:43:12

US3752259
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
Data entry locked.	System	26 Aug 2020 15:44:50
User entered '26 Oct 2020 00:01'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181675

US3752259
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
Data entry locked.	System	26 Aug 2020 15:44:50
User entered '30 Oct 2020 23:59'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181676

US3752259
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
Data entry locked.	System	26 Aug 2020 15:44:50
User entered 'Day 71'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181677

US3752259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:47:59

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-11-02T06:46:14', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '1c069580-4273-4ffa-ad1a-95f13e1e06e3'	System	02 Nov 2020 12:46:32
User entered 'No (N)'	System	02 Nov 2020 12:46:32

US3752259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:47:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-11-02T06:46:21', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '1c069580-4273-4ffa-ad1a-95f13e1e06e3'	System	02 Nov 2020 12:46:32
User entered 'No (N)'	System	02 Nov 2020 12:46:32

US3752259
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-11-02T06:46:29', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '1c069580-4273-4ffa-ad1a-95f13e1e06e3'	System	02 Nov 2020 12:46:32
User entered '02 Nov 2020 06:46:29'	System	02 Nov 2020 12:46:32

FDA-CBER-2022-1614-3181680

US3752259
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
Data entry locked.	System	26 Aug 2020 15:44:50
User entered '02 Nov 2020 00:01'	System	26 Aug 2020 15:44:50

US3752259
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
Data entry locked.	System	26 Aug 2020 15:44:50
User entered '06 Nov 2020 23:59'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181682

US3752259
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
Data entry locked.	System	26 Aug 2020 15:44:50
User entered 'Day 78'	System	26 Aug 2020 15:44:50

US3752259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:47:59

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-11-09T00:08:32', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'c2f9e24e-6d1e-4344-b1bb-75161563ef12'	System	09 Nov 2020 06:08:44
User entered 'No (N)'	System	09 Nov 2020 06:08:44

US3752259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:47:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-11-09T00:08:37', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'c2f9e24e-6d1e-4344-b1bb-75161563ef12'	System	09 Nov 2020 06:08:44
User entered 'No (N)'	System	09 Nov 2020 06:08:44

US3752259
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-11-09T00:08:42', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'c2f9e24e-6d1e-4344-b1bb-75161563ef12'	System	09 Nov 2020 06:08:44
User entered '09 Nov 2020 00:08:42'	System	09 Nov 2020 06:08:44

FDA-CBER-2022-1614-3181686

US3752259
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
Data entry locked.	System	26 Aug 2020 15:44:50
User entered '09 Nov 2020 00:01'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181687

US3752259
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:55:40
Data entry locked.	System	26 Aug 2020 15:44:50
User entered '13 Nov 2020 23:59'	System	26 Aug 2020 15:44:50

FDA-CBER-2022-1614-3181688

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:37
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 18:04:37

FDA-CBER-2022-1614-3181689

US3752259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:47:59

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04

US3752259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:47:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04

US3752259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:47:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04

US3752259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:47:59

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04

FDA-CBER-2022-1614-3181695

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04

FDA-CBER-2022-1614-3181696

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04

FDA-CBER-2022-1614-3181697

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04

FDA-CBER-2022-1614-3181698

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04

FDA-CBER-2022-1614-3181699

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04

FDA-CBER-2022-1614-3181700

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04

FDA-CBER-2022-1614-3181701

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04

FDA-CBER-2022-1614-3181702

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04

FDA-CBER-2022-1614-3181703

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04

FDA-CBER-2022-1614-3181704

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04

FDA-CBER-2022-1614-3181705

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04

FDA-CBER-2022-1614-3181706

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04

FDA-CBER-2022-1614-3181707

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04

FDA-CBER-2022-1614-3181708

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04

FDA-CBER-2022-1614-3181709

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04

FDA-CBER-2022-1614-3181710

US3752259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:47:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04

US3752259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:47:59

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04

US3752259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:47:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:37
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 18:04:37

FDA-CBER-2022-1614-3181715

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:37
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 18:04:37

FDA-CBER-2022-1614-3181716

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:37
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 18:04:37

US3752259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:47:59

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-11-27T00:01:39', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'f6e90e99-5d12-49a6-a492-8f2ce528ee35'	System	27 Nov 2020 06:01:57
User entered 'No (N)'	System	27 Nov 2020 06:01:57

US3752259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:47:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-11-27T00:01:45', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'f6e90e99-5d12-49a6-a492-8f2ce528ee35'	System	27 Nov 2020 06:01:57
User entered 'No (N)'	System	27 Nov 2020 06:01:57

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-11-27T00:01:52', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'f6e90e99-5d12-49a6-a492-8f2ce528ee35'	System	27 Nov 2020 06:01:57
User entered '27 Nov 2020 00:01:52'	System	27 Nov 2020 06:01:57

FDA-CBER-2022-1614-3181720

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:37
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 18:04:37

FDA-CBER-2022-1614-3181721

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:37
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 18:04:37

FDA-CBER-2022-1614-3181722

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:37
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 18:04:37

FDA-CBER-2022-1614-3181723

US3752259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:47:59

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-12-04T00:02:12', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '774aa08c-00b1-49dd-9d1b-bab3a6e8ed32'	System	04 Dec 2020 06:02:26
User entered 'No (N)'	System	04 Dec 2020 06:02:26

US3752259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:47:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-12-04T00:02:16', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '774aa08c-00b1-49dd-9d1b-bab3a6e8ed32'	System	04 Dec 2020 06:02:26
User entered 'No (N)'	System	04 Dec 2020 06:02:26

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-12-04T00:02:21', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '774aa08c-00b1-49dd-9d1b-bab3a6e8ed32'	System	04 Dec 2020 06:02:26
User entered '04 Dec 2020 00:02:21'	System	04 Dec 2020 06:02:26

FDA-CBER-2022-1614-3181726

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:37
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 18:04:37

FDA-CBER-2022-1614-3181727

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:37
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 18:04:37

FDA-CBER-2022-1614-3181728

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:37
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 18:04:37

FDA-CBER-2022-1614-3181729

US3752259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:47:59

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-12-11T00:01:42', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '5a5e7a08-8f86-460a-b124-37ffef8a53ce'	System	11 Dec 2020 06:02:14
User entered 'No (N)'	System	11 Dec 2020 06:02:14

US3752259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:47:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-12-11T00:01:48', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '5a5e7a08-8f86-460a-b124-37ffef8a53ce'	System	11 Dec 2020 06:02:14
User entered 'No (N)'	System	11 Dec 2020 06:02:14

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-12-11T00:02:11', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '5a5e7a08-8f86-460a-b124-37ffef8a53ce'	System	11 Dec 2020 06:02:14
User entered '11 Dec 2020 00:02:11'	System	11 Dec 2020 06:02:14

FDA-CBER-2022-1614-3181732

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:37
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 18:04:37

FDA-CBER-2022-1614-3181733

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:37
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 18:04:37

FDA-CBER-2022-1614-3181734

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:37
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 18:04:37

US3752259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:47:59

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-12-18T00:13:43', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'b4e7a97d-7378-43cc-a686-6c31288bdf1c'	System	18 Dec 2020 06:13:56
User entered 'No (N)'	System	18 Dec 2020 06:13:56

US3752259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:47:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-12-18T00:13:51', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'b4e7a97d-7378-43cc-a686-6c31288bdf1c'	System	18 Dec 2020 06:13:56
User entered 'No (N)'	System	18 Dec 2020 06:13:56

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-12-18T00:13:55', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'b4e7a97d-7378-43cc-a686-6c31288bdf1c'	System	18 Dec 2020 06:13:56
User entered '18 Dec 2020 00:13:55'	System	18 Dec 2020 06:13:56

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:37
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 18:04:37

FDA-CBER-2022-1614-3181739

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:37
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 18:04:37

FDA-CBER-2022-1614-3181740

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:37
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 18:04:37

FDA-CBER-2022-1614-3181741

US3752259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:47:59

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-12-25T06:26:10', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '568106d2-dd48-4a13-beab-6828b546e64e'	System	25 Dec 2020 12:27:16
User entered 'Yes (Y)'	System	25 Dec 2020 12:27:16

US3752259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:47:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-12-25T06:26:15', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '568106d2-dd48-4a13-beab-6828b546e64e'	System	25 Dec 2020 12:27:16
User entered 'No (N)'	System	25 Dec 2020 12:27:16

US3752259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:47:59

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-12-25T06:26:21', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '568106d2-dd48-4a13-beab-6828b546e64e'	System	25 Dec 2020 12:27:16
User entered 'No (N)'	System	25 Dec 2020 12:27:16

US3752259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:47:59

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-12-25T06:26:35', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '568106d2-dd48-4a13-beab-6828b546e64e'	System	25 Dec 2020 12:27:16
User entered 'Yes (Y)'	System	25 Dec 2020 12:27:16

US3752259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:47:59

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-12-25T06:26:55', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '568106d2-dd48-4a13-beab-6828b546e64e'	System	25 Dec 2020 12:27:16
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	25 Dec 2020 12:27:16

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2020-12-25T06:27:01', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '568106d2-dd48-4a13-beab-6828b546e64e'	System	25 Dec 2020 12:27:16
User entered '25 Dec 2020 06:27:01'	System	25 Dec 2020 12:27:16

FDA-CBER-2022-1614-3181747

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:37
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 18:04:37

FDA-CBER-2022-1614-3181748

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:37
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 18:04:37

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:37
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 18:04:37

FDA-CBER-2022-1614-3181750

US3752259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:47:59

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2021-01-03T12:03:42', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '32f8fdca-5325-47af-a733-f7cbd5cc20b8'	System	03 Jan 2021 18:03:58
User entered 'No (N)'	System	03 Jan 2021 18:03:58

US3752259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:47:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2021-01-03T12:03:46', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '32f8fdca-5325-47af-a733-f7cbd5cc20b8'	System	03 Jan 2021 18:03:58
User entered 'No (N)'	System	03 Jan 2021 18:03:58

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2021-01-03T12:03:53', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '32f8fdca-5325-47af-a733-f7cbd5cc20b8'	System	03 Jan 2021 18:03:58
User entered '03 Jan 2021 12:03:53'	System	03 Jan 2021 18:03:58

FDA-CBER-2022-1614-3181753

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:37
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 18:04:37

FDA-CBER-2022-1614-3181754

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:37
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 18:04:37

FDA-CBER-2022-1614-3181755

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:37
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 18:04:37

US3752259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:47:59

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2021-01-08T07:03:59', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '73da2f96-bc0b-4ed0-9bf0-1109471938b9'	System	08 Jan 2021 13:04:21
User entered 'No (N)'	System	08 Jan 2021 13:04:21

US3752259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:47:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2021-01-08T07:04:05', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '73da2f96-bc0b-4ed0-9bf0-1109471938b9'	System	08 Jan 2021 13:04:21
User entered 'No (N)'	System	08 Jan 2021 13:04:21

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2021-01-08T07:04:16', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: '73da2f96-bc0b-4ed0-9bf0-1109471938b9'	System	08 Jan 2021 13:04:21
User entered '08 Jan 2021 07:04:16'	System	08 Jan 2021 13:04:21

FDA-CBER-2022-1614-3181759

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:37
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 18:04:37

FDA-CBER-2022-1614-3181760

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:37
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 18:04:37

FDA-CBER-2022-1614-3181761

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:37
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 18:04:37

FDA-CBER-2022-1614-3181762

US3752259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:47:59

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2021-01-15T00:01:46', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'aa3665eb-18ef-449c-adbd-5d37aba352a9'	System	15 Jan 2021 06:02:13
User entered 'No (N)'	System	15 Jan 2021 06:02:13

US3752259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:47:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2021-01-15T00:01:52', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'aa3665eb-18ef-449c-adbd-5d37aba352a9'	System	15 Jan 2021 06:02:13
User entered 'No (N)'	System	15 Jan 2021 06:02:13

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2021-01-15T00:02:04', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'aa3665eb-18ef-449c-adbd-5d37aba352a9'	System	15 Jan 2021 06:02:13
User entered '15 Jan 2021 00:02:04'	System	15 Jan 2021 06:02:13

FDA-CBER-2022-1614-3181765

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:37
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 18:04:37

FDA-CBER-2022-1614-3181766

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:37
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 18:04:37

FDA-CBER-2022-1614-3181767

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:37
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 18:04:37

FDA-CBER-2022-1614-3181768

US3752259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:47:59

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2021-01-22T00:09:47', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'b65c9dc1-7729-4d61-888e-16599fbe14b8'	System	22 Jan 2021 06:10:02
User entered 'No (N)'	System	22 Jan 2021 06:10:02

US3752259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:47:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2021-01-22T00:09:51', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'b65c9dc1-7729-4d61-888e-16599fbe14b8'	System	22 Jan 2021 06:10:02
User entered 'No (N)'	System	22 Jan 2021 06:10:02

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2021-01-22T00:09:55', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'b65c9dc1-7729-4d61-888e-16599fbe14b8'	System	22 Jan 2021 06:10:02
User entered '22 Jan 2021 00:09:55'	System	22 Jan 2021 06:10:02

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:37
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 18:04:37

FDA-CBER-2022-1614-3181772

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:37
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 18:04:37

FDA-CBER-2022-1614-3181773

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:37
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 18:04:37

FDA-CBER-2022-1614-3181774

US3752259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:47:59

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2021-01-29T07:05:49', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'b69f2cd9-f205-4099-a4ef-35b48f625f9c'	System	29 Jan 2021 13:06:03
User entered 'No (N)'	System	29 Jan 2021 13:06:03

US3752259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:47:59

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2021-01-29T07:05:55', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'b69f2cd9-f205-4099-a4ef-35b48f625f9c'	System	29 Jan 2021 13:06:03
User entered 'No (N)'	System	29 Jan 2021 13:06:03

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B06286FA-E6E4-40D2-8FCC-299A930A5E97)', Time: '2021-01-29T07:05:58', User OID: 'PatientReportedOutcome (US3752259)', ODM File OID: 'b69f2cd9-f205-4099-a4ef-35b48f625f9c'	System	29 Jan 2021 13:06:03
User entered '29 Jan 2021 07:05:58'	System	29 Jan 2021 13:06:03

FDA-CBER-2022-1614-3181777

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:37
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 18:04:37

FDA-CBER-2022-1614-3181778

US3752259
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 09:47:59
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:04:37
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 18:04:37

US3752259
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:47:59
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:50:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Nov 2020 16:22:55

US3752259
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:47:59
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:50:09
User entered '18 Nov 2020'	(b) (4), (b) (6)	18 Nov 2020 16:22:55

FDA-CBER-2022-1614-3181781

US3752259
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:47:59
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:50:11
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	18 Nov 2020 16:22:55

FDA-CBER-2022-1614-3181782

US3752259
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:47:59
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 15:50:12
User entered empty.	(b) (4), (b) (6)	18 Nov 2020 16:22:55

FDA-CBER-2022-1614-3181783

US3752259
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:47:59
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:50:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Nov 2020 16:22:59

FDA-CBER-2022-1614-3181784

US3752259
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:47:59
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '1'	System	18 Nov 2020 16:22:59

FDA-CBER-2022-1614-3181785

US3752259
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:47:59
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:51:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:36:31

FDA-CBER-2022-1614-3181786

US3752259
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:47:59
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User closed query 'please complete OL-D1 tab per source' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 15:01:25
Query 'please complete OL-D1 tab per source' answered with 'done' (Site from CRA).	Jamie Pettus (b) (4) (b) (4)	11 Mar 2021 20:14:07
User opened query 'please complete OL-D1 tab per source' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 21:11:26
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:51:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
User entered '22 Dec 2020'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:36:31

FDA-CBER-2022-1614-3181787

US3752259
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:47:59
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:51:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	22 Dec 2020 16:36:31

FDA-CBER-2022-1614-3181788

US3752259
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:47:59
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:51:02
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:36:31

FDA-CBER-2022-1614-3181789

US3752259
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:47:59
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:11:12
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 16:36:43

FDA-CBER-2022-1614-3181790

US3752259
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:47:59
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '1'	System	22 Dec 2020 16:36:43

FDA-CBER-2022-1614-3181791

US3752259
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:47:59
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:12:45
User signature succeeded.	Priyantha Wijewardane (b) (4)	16 Mar 2021 13:08:17
User entered 'Yes (Y)'	Lauren Evans (b) (4)	15 Mar 2021 20:29:00

FDA-CBER-2022-1614-3181792

US3752259
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:47:59
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:12:45
User signature succeeded.	Priyantha Wijewardane (b) (4)	16 Mar 2021 13:08:17
User entered '21 Jan 2021'	Lauren Evans (b) (4)	15 Mar 2021 20:29:00

US3752259
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:47:59
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:12:45
User signature succeeded.	Priyantha Wijewardane	16 Mar 2021 13:08:17
User entered 'Contact Made (CONTACT MADE)'	Lauren Evans (b) (4)	15 Mar 2021 20:29:00

FDA-CBER-2022-1614-3181794

US3752259
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 10 Jun 2021 09:47:59
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:12:45
User signature succeeded.	Priyantha Wijewardane (b) (4)	16 Mar 2021 13:08:17
User entered empty.	Lauren Evans (b) (4)	15 Mar 2021 20:29:00

FDA-CBER-2022-1614-3181795

US3752259
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:47:59
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:13:16
User signature succeeded.	Priyantha Wijewardane (b) (4)	17 Mar 2021 20:27:57
User entered 'No (N)'	Lauren Evans (b) (4)	16 Mar 2021 19:31:58

FDA-CBER-2022-1614-3181796

US3752259
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 10 Jun 2021 09:47:59
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	16 Mar 2021 19:31:58

FDA-CBER-2022-1614-3181797

US3752259
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:47:59
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:13:32
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:22:02
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 20:22:53

FDA-CBER-2022-1614-3181798

US3752259
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:47:59
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:13:32
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:22:02
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 20:22:53

FDA-CBER-2022-1614-3181799

US3752259
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:47:59
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 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:13:32
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:22:02
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 20:22:53

FDA-CBER-2022-1614-3181800

US3752259
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 10 Jun 2021 09:47:59
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered 'UNBLND_DECIDE'	System	11 Mar 2021 20:22:53

US3752259
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:47:59
Date of updated informed consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane (b) (4)	23 Apr 2021 14:52:04
User closed query 'Per sponsor review, the date of updated informed consent" and "N/A - Subject Unblinded under Amendment 5 and Discontinued from Study" cannot both be blank. Please either update date subject signed updated informed consent or if Subject discontinued from the study under Amendment 5, tick the box." ' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 06:59:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:14:14
Query 'Per sponsor review, the date of updated informed consent" and "N/A - Subject Unblinded under Amendment 5 and Discontinued from Study" cannot both be blank. Please either update date subject signed updated informed consent or if Subject discontinued from the study under Amendment 5, tick the box." ' answered with 'Updated. Can you please advise if the date of updated informed consent should be the date of the amended ICF they are signing? This is what we were told ' (Site from DM).	Haylee Rowe (b) (4) (b) (4)	07 Apr 2021 16:45:37
Signature has been broken.	Haylee Rowe (b) (4) (b) (4)	07 Apr 2021 16:45:19
User entered '06 Jan 2021' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	07 Apr 2021 16:45:19
User opened query 'Per sponsor review, the date of updated informed consent" and "N/A - Subject Unblinded under Amendment 5 and Discontinued from Study" cannot both be blank. Please either update date subject signed updated informed consent or if Subject discontinued from the study under Amendment 5, tick the box." ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 15:50:51
User signature succeeded.	Priyantha Wijewardane (b) (4)	31 Mar 2021 14:20:26
User entered empty.	Lauren Evans (b) (4)	30 Mar 2021 14:43:04

FDA-CBER-2022-1614-3181802

US3752259
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:47:59
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:14:14
User signature succeeded.	Priyantha Wijewardane (b) (4)	31 Mar 2021 14:20:26
User entered '0'	Lauren Evans (b) (4)	30 Mar 2021 14:43:04

US3752259
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:47:59
Was the participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:14:14
User signature succeeded.	Priyantha Wijewardane (b) (4)	31 Mar 2021 14:20:26
User entered 'Yes (Y)'	Lauren Evans (b) (4)	30 Mar 2021 14:43:04

US3752259
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:47:59
Under what version of the Protocol was the Participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:14:14
User signature succeeded.	Priyantha Wijewardane	31 Mar 2021 14:20:26
User entered 'Amendment 6 or later (Amendment 6 or later)'	Lauren Evans (b) (4)	30 Mar 2021 14:43:04

US3752259
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:47:59
Date of unblinding *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:14:14
User signature succeeded.	Priyantha Wijewardane (b) (4)	31 Mar 2021 14:20:26
User entered '03 Feb 2021'	Lauren Evans (b) (4)	30 Mar 2021 14:43:04

FDA-CBER-2022-1614-3181806

US3752259
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:47:59
Participant randomization assignment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:14:14
User signature succeeded.	Priyantha Wijewardane (b) (4)	31 Mar 2021 14:20:26
User entered 'Placebo (Placebo)'	Lauren Evans (b) (4)	30 Mar 2021 14:43:04

FDA-CBER-2022-1614-3181807

US3752259
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:47:59
Actual Dose 1

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:14:14
User signature succeeded.	Priyantha Wijewardane (b) (4)	31 Mar 2021 14:20:26
User entered 'Placebo (Placebo)'	Lauren Evans (b) (4)	30 Mar 2021 14:43:04

FDA-CBER-2022-1614-3181808

US3752259
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:47:59
Actual Dose 2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:14:14
User signature succeeded.	Priyantha Wijewardane (b) (4)	31 Mar 2021 14:20:26
User entered 'Placebo (Placebo)'	Lauren Evans (b) (4)	30 Mar 2021 14:43:04

US3752259
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:47:59
Will participant receive mRNA-1273?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:14:14
User signature succeeded.	Priyantha Wijewardane (b) (4)	31 Mar 2021 14:20:26
User entered 'No (N)'	Lauren Evans (b) (4)	30 Mar 2021 14:43:04

US3752259
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:47:59
Placebo Only Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '1'	System	30 Mar 2021 14:43:04

FDA-CBER-2022-1614-3181811

US3752259
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 09:47:59
Continuing with mRNA-1273

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	30 Mar 2021 14:43:04

FDA-CBER-2022-1614-3181812

US3752259
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:47:59
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:14:24
User signature succeeded.	Priyantha Wijewardane (b) (4)	31 Mar 2021 14:20:26
User entered 'No (N)'	Lauren Evans (b) (4)	30 Mar 2021 16:28:04

US3752259
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:47:59
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:14:24
User signature succeeded.	Priyantha Wijewardane (b) (4)	31 Mar 2021 14:20:26
User entered empty.	Lauren Evans (b) (4)	30 Mar 2021 16:28:04

FDA-CBER-2022-1614-3181814

US3752259
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:47:59
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:14:24
User signature succeeded.	Priyantha Wijewardane (b) (4)	31 Mar 2021 14:20:26
User entered empty.	Lauren Evans (b) (4)	30 Mar 2021 16:28:04

US3752259
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 09:47:59
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	30 Mar 2021 16:28:04

FDA-CBER-2022-1614-3181816

US3752259
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 10 Jun 2021 09:47:59
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:11:55
User signature succeeded.	Priyantha Wijewardane (b) (4)	31 Mar 2021 14:20:26
User entered 'No (N)'	Lauren Evans (b) (4)	30 Mar 2021 16:28:00

US3752259
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 10 Jun 2021 09:47:59
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:11:55
User signature succeeded.	Priyantha Wijewardane (b) (4)	31 Mar 2021 14:20:26
User entered empty.	Lauren Evans (b) (4)	30 Mar 2021 16:28:00

US3752259
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 10 Jun 2021 09:47:59
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:11:55
User signature succeeded.	Priyantha Wijewardane (b) (4)	31 Mar 2021 14:20:26
User entered empty.	Lauren Evans (b) (4)	30 Mar 2021 16:28:00

US3752259
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 10 Jun 2021 09:47:59
Collection Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	30 Mar 2021 16:28:00

FDA-CBER-2022-1614-3181820

US3752259
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 10 Jun 2021 09:47:59
Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:54:38
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
DataPoint Un-verified.	Lauren Evans (b) (4)	22 Dec 2020 18:38:13
User entered 'Yes (Y)' reason for change: Data Entry Error	Lauren Evans (b) (4)	22 Dec 2020 18:38:13
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 15:58:33
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 15:19:01

US3752259
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:47:59
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:55:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:52:03
User entered 'USA-US113-2020-mRNA-1273-P301000015'	System	22 Dec 2020 20:51:57
User entered 'New'	(b) (4), (b) (6)	22 Dec 2020 20:51:57

FDA-CBER-2022-1614-3181822

US3752259
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:47:59
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:17:30
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial flutter, LLT: Atrial flutter - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Mar 2021 16:08:30
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Mar 2021 16:08:30
User signature succeeded.	Priyantha Wijewardane (b) (4)	27 Mar 2021 14:58:05
Data point term sent to Coder	System	26 Mar 2021 20:25:00
Coding entries removed.	Haylee Rowe (b) (4) (b) (4)	26 Mar 2021 20:24:52
Signature has been broken.	Haylee Rowe (b) (4) (b) (4)	26 Mar 2021 20:24:52
User entered 'SIMULTANEOUS OCCURRENCE OF ATRIAL FLUTTER' reason for change: Per Query Resolution	Haylee Rowe (b) (4) (b) (4)	26 Mar 2021 20:24:52
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Mar 2021 13:58:21
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Mar 2021 13:58:21
User signature succeeded.	Priyantha Wijewardane (b) (4)	20 Mar 2021 01:42:20
User closed query 'please add atrial fibrillation also per hosp record' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 14:53:20
User closed query 'PV Query: The event term ‘atrial flutter/fibrillation' contains multiple event terms. Please consider separating them into separate events. ' (Site from Safety).	(b) (4), (b) (6)	17 Mar 2021 15:50:53
Data point term sent to Coder	System	16 Mar 2021 19:13:35
User closed query 'For coding purposes, please split ATRIAL FLUTTER/FIBRILATION into separate entries or provide ONE diagnosis.' (Site from System).	System	16 Mar 2021 19:12:54
Query 'For coding purposes, please split ATRIAL FLUTTER/FIBRILATION into separate entries or provide ONE diagnosis.' answered with 'updated' (Site from System).	Jamie Pettus (b) (4) (b) (4)	16 Mar 2021 19:12:54

FDA-CBER-2022-1614-3181823

US3752259
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:47:59
Adverse event

Audit	User	Time (GMT)
Query 'PV Query: The event term ‘atrial flutter/fibrillation' contains multiple event terms. Please consider separating them into separate events. ' answered with 'updated' (Site from Safety).	Jamie Pettus (b) (4) (b) (4)	16 Mar 2021 19:12:37
Data point term sent to Coder	System	16 Mar 2021 19:12:34
User entered 'Simultaneous occurrence of atrial fibrillation and atrial flutter' reason for change: Per Query Resolution	Jamie Pettus (b) (4) (b) (4)	16 Mar 2021 19:12:27
User opened query 'For coding purposes, please split ATRIAL FLUTTER/FIBRILATION into separate entries or provide ONE diagnosis.' (Site from System).	Coder Import (b) (4) (b) (4)	16 Mar 2021 16:49:55
User opened query 'PV Query: The event term ‘atrial flutter/fibrillation' contains multiple event terms. Please consider separating them into separate events. ' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 13:38:34
Data point term sent to Coder	System	11 Mar 2021 20:16:12
User closed query 'For coding purposes, please split ATRIAL FLUTTER/FIBRILATION into separate entries. 1. Atrial flutter nand 2. Atrial Fibilation' (Site from System).	System	11 Mar 2021 20:16:11
Query 'For coding purposes, please split ATRIAL FLUTTER/FIBRILATION into separate entries. 1. Atrial flutter nand 2. Atrial Fibilation' answered with 'Done this way per CRA instruction' (Site from System).	Jamie Pettus (b) (4) (b) (4)	11 Mar 2021 20:16:11
User opened query 'For coding purposes, please split ATRIAL FLUTTER/FIBRILATION into separate entries. 1. Atrial flutter nand 2. Atrial Fibilation' (Site from System).	Coder Import (b) (4) (b) (4)	10 Mar 2021 20:44:59
Data point term sent to Coder	System	09 Mar 2021 20:47:40
Query 'please add atrial fibrillation also per hosp record' answered with 'updated' (Site from CRA).	Jamie Pettus (b) (4) (b) (4)	09 Mar 2021 20:47:37
DataPoint Un-verified.	Jamie Pettus (b) (4) (b) (4)	09 Mar 2021 20:47:29
Coding entries removed.	Jamie Pettus (b) (4) (b) (4)	09 Mar 2021 20:47:29
Signature has been broken.	Jamie Pettus (b) (4) (b) (4)	09 Mar 2021 20:47:29
User entered 'ATRIAL FLUTTER/fibrilation' reason for change: Data Entry Error	Jamie Pettus (b) (4) (b) (4)	09 Mar 2021 20:47:29

FDA-CBER-2022-1614-3181824

US3752259
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:47:59
Adverse event

Audit	User	Time (GMT)
User opened query 'please add atrial fibrillation also per hosp record' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 21:14:00
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:55:14
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial flutter, LLT: Atrial flutter - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Dec 2020 18:43:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Dec 2020 18:43:46
Data point term sent to Coder	System	22 Dec 2020 18:43:36
User entered 'Atrial Flutter'	Lauren Evans (b) (4)	22 Dec 2020 18:43:18

US3752259
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:47:59
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:55:14
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'Yes (Y)'	Lauren Evans (b) (4)	22 Dec 2020 18:43:18

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US3752259
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:47:59
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:55:14
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'No (N)'	Lauren Evans (b) (4)	22 Dec 2020 18:43:18

US3752259
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:47:59
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:55:14
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'No (N)'	Lauren Evans (b) (4)	22 Dec 2020 18:43:18

FDA-CBER-2022-1614-3181828

US3752259
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:47:59
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:55:14
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered '20 Dec 2020'	Lauren Evans (b) (4)	22 Dec 2020 18:43:18

FDA-CBER-2022-1614-3181829

US3752259
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:47:59
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:55:14
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered empty.	Lauren Evans (b) (4)	22 Dec 2020 18:43:18

FDA-CBER-2022-1614-3181830

US3752259
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:47:59
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	22 Dec 2020 18:43:18

FDA-CBER-2022-1614-3181831

US3752259
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:47:59
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:55:14
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'No (N)'	Lauren Evans (b) (4)	22 Dec 2020 18:43:18

FDA-CBER-2022-1614-3181832

US3752259
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:47:59
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:55:14
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered '21 Dec 2020'	Lauren Evans (b) (4)	22 Dec 2020 18:43:18

US3752259
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:47:59
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:55:14
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered empty.	Lauren Evans (b) (4)	22 Dec 2020 18:43:18

FDA-CBER-2022-1614-3181834

US3752259
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:47:59
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	22 Dec 2020 18:43:18

FDA-CBER-2022-1614-3181835

US3752259
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:47:59
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:55:14
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'Grade 4 (Grade 4)'	Lauren Evans (b) (4)	22 Dec 2020 18:43:18

FDA-CBER-2022-1614-3181836

US3752259
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:47:59
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:55:14
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'Yes (Y)'	Lauren Evans (b) (4)	22 Dec 2020 18:43:18

US3752259
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:47:59
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:55:14
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered '0'	Lauren Evans (b) (4)	22 Dec 2020 18:43:18

FDA-CBER-2022-1614-3181838

US3752259
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:47:59
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:55:14
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered '0'	Lauren Evans (b) (4)	22 Dec 2020 18:43:18

FDA-CBER-2022-1614-3181839

US3752259
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:47:59
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:55:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
User closed query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' (Site from Safety).	(b) (4) (b) (4), (b) (6)	04 Jan 2021 14:26:42
Query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' answered with 'Subject was hospitalized overnight.' (Site from Safety).	(b) (4), (b) (6)	30 Dec 2020 15:52:00
User opened query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' (Site from Safety).	(b) (4), (b) (6)	28 Dec 2020 20:50:29
User entered '1'	Lauren Evans (b) (4)	22 Dec 2020 18:43:18

FDA-CBER-2022-1614-3181840

US3752259
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:47:59
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:55:14
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered '20 Dec 2020'	Lauren Evans (b) (4)	22 Dec 2020 18:43:18

FDA-CBER-2022-1614-3181841

US3752259
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:47:59
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:55:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	04 Jan 2021 14:26:41
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Discharge summary faxed to 866.599.1342.' (Site from Safety).	(b) (4), (b) (6)	30 Dec 2020 16:01:05
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	28 Dec 2020 20:50:17
User entered '21 Dec 2020'	Lauren Evans (b) (4)	22 Dec 2020 18:43:18

FDA-CBER-2022-1614-3181842

US3752259
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:47:59
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:55:14
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'No (N)'	Lauren Evans (b) (4)	22 Dec 2020 18:43:18

FDA-CBER-2022-1614-3181843

US3752259
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:47:59
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:55:14
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered empty.	Lauren Evans (b) (4)	22 Dec 2020 18:43:18

FDA-CBER-2022-1614-3181844

US3752259
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:47:59
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:55:14
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered '0'	Lauren Evans (b) (4)	22 Dec 2020 18:43:18

US3752259
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:47:59
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:55:14
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered '0'	Lauren Evans (b) (4)	22 Dec 2020 18:43:18

US3752259
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:47:59
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:55:14
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered '0'	Lauren Evans (b) (4)	22 Dec 2020 18:43:18

US3752259
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:47:59
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:55:14
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Dec 2020 19:32:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Dec 2020 19:32:42
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Dec 2020 19:32:42
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Dec 2020 18:43:18
User entered empty.	Lauren Evans (b) (4)	22 Dec 2020 18:43:18

FDA-CBER-2022-1614-3181848

US3752259
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:47:59
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:55:14
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Dec 2020 19:32:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Dec 2020 19:32:42
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Dec 2020 19:32:42
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Dec 2020 18:43:18
User entered empty.	Lauren Evans (b) (4)	22 Dec 2020 18:43:18

FDA-CBER-2022-1614-3181849

US3752259
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:47:59
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:55:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
User closed query 'PV Query: As the last dose of study drug was given on 23Sep2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:38:41
Query 'PV Query: As the last dose of study drug was given on 23Sep2020, please update the action taken with study drug from none to not applicable.' answered with 'done' (Site from Safety).	(b) (4), (b) (6)	29 Dec 2020 15:48:25
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 15:47:52
User opened query 'PV Query: As the last dose of study drug was given on 23Sep2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	28 Dec 2020 20:49:58
User entered 'None (NONE)'	Lauren Evans (b) (4)	22 Dec 2020 18:43:18

US3752259
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:47:59
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:55:14
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered '0'	Lauren Evans (b) (4)	22 Dec 2020 18:43:18

US3752259
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:47:59
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:55:14
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered '1'	Lauren Evans (b) (4)	22 Dec 2020 18:43:18

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US3752259
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:47:59
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:55:14
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered '1'	Lauren Evans (b) (4)	22 Dec 2020 18:43:18

US3752259
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:47:59
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:17:30
User closed query 'PV Query: Subject is reported to be receiving Eliquis and amiodarone for atrial flutter. If anticoagulation and rhythm control treatment will continue to be administered long term, please consider updating event outcome from resolved to resolved with sequel as applicable.' (Site from Safety).	(b) (4), (b) (6)	07 Apr 2021 15:43:19
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Apr 2021 23:22:03
Query 'PV Query: Subject is reported to be receiving Eliquis and amiodarone for atrial flutter. If anticoagulation and rhythm control treatment will continue to be administered long term, please consider updating event outcome from resolved to resolved with sequel as applicable.' answered with 'Updated for query resolution. This subject is no longer in the study. ' (Site from Safety).	Haylee Rowe (b) (4) (b) (4)	06 Apr 2021 21:12:15
DataPoint Un-verified.	Haylee Rowe (b) (4) (b) (4)	06 Apr 2021 21:10:59
Signature has been broken.	Haylee Rowe (b) (4) (b) (4)	06 Apr 2021 21:10:59
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	06 Apr 2021 21:10:59
User opened query 'PV Query: Subject is reported to be receiving Eliquis and amiodarone for atrial flutter. If anticoagulation and rhythm control treatment will continue to be administered long term, please consider updating event outcome from resolved to resolved with sequel as applicable.' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 21:21:38
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:55:14
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Lauren Evans (b) (4)	22 Dec 2020 18:43:18

FDA-CBER-2022-1614-3181854

US3752259
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:47:59
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 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:17:30
User signature succeeded.	Priyantha Wijewardane (b) (4)	06 Apr 2021 23:22:03
User closed query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	06 Apr 2021 21:12:38
DataPoint Un-verified.	Haylee Rowe (b) (4) (b) (4)	06 Apr 2021 21:12:38
Signature has been broken.	Haylee Rowe (b) (4) (b) (4)	06 Apr 2021 21:12:38
User entered 'Patient is taking Eliquis and amiodarone for this adverse event.' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	06 Apr 2021 21:12:38
User opened query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	06 Apr 2021 21:10:59
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:55:14
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered empty.	Lauren Evans (b) (4)	22 Dec 2020 18:43:18

US3752259
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:47:59
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User closed query 'PV query: Thank you for updating the event term, please consider splitting events into two separate Adverse Event eCRF's.' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 16:46:26
Query 'PV query: Thank you for updating the event term, please consider splitting events into two separate Adverse Event eCRF's.' answered with 'Events split into two separate AEs for query resolution and patient preference ' (Site from Safety).	Haylee Rowe (b) (4) (b) (4)	26 Mar 2021 20:32:19
User opened query 'PV query: Thank you for updating the event term, please consider splitting events into two separate Adverse Event eCRF's.' (Site from Safety).	(b) (4), (b) (6)	26 Mar 2021 15:31:16
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:55:14
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User closed query 'PV Query: Please resend a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, as we do not receive anything. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 15:59:10
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 15:59:08
Query 'PV Query: Please resend a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, as we do not receive anything. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' answered with 'sent' (Site from Safety).	Jamie Pettus (b) (4) (b) (4)	13 Jan 2021 22:00:08

US3752259
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:47:59
Narrative

Audit	User	Time (GMT)
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'Not done' (Site from Safety).	Jamie Pettus (b) (4) (b) (4)	13 Jan 2021 21:24:57
User opened query 'PV Query: Please resend a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, as we do not receive anything. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	13 Jan 2021 16:26:21
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	06 Jan 2021 15:05:37
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable' canceled (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 18:48:01
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 18:47:11
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 18:46:02
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'ABNORMAL EKG, TRANSESOPHAGEAL ECHOCARDIOGRAM WITH CARDIOVERSION - RIGHT/EFT ATRIUM MODERATELY DILATED, MITRAL VALVE SCLEROSIS WITH MILD MITRAL REGURGITATION' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 16:27:37
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	28 Dec 2020 20:50:07

US3752259
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:47:59
Narrative

Audit	User	Time (GMT)
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	28 Dec 2020 19:59:36
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	28 Dec 2020 19:59:36
User entered 'ADMITTED 20DEC2020WITH NEW ONSET A.FLUTTER. S/P CARDIOVERSION 21DEC2020. D/C HOME ON 21DEC2020. ASYMPTOMATIC AT DOSING.' reason for change: Data Entry Error	Amanda Horn (b) (4) (b) (4)	28 Dec 2020 19:59:36
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	22 Dec 2020 18:43:18
User entered empty.	Lauren Evans (b) (4)	22 Dec 2020 18:43:18

US3752259
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:47:59
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '1'	System	22 Dec 2020 18:43:18

US3752259
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:47:59
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '1'	System	22 Dec 2020 18:43:18

US3752259
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 10 Jun 2021 09:47:59
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '0'	System	22 Dec 2020 18:43:18

US3752259
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:47:59
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:17:30
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 15:43:24
User signature succeeded.	Priyantha Wijewardane	31 Mar 2021 14:20:26
User entered 'USA-US113-2020-mRNA-1273-P301000015'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:45:01

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US3752259
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:47:59
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User closed query 'Per DM CLR: Please review if this event is a duplicate of AE#1. If so, please delete entry. Else, review dates so there are no overlapping dates or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 06:55:50
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:17:30
Query 'Per DM CLR: Please review if this event is a duplicate of AE#1. If so, please delete entry. Else, review dates so there are no overlapping dates or provide clarification. ' answered with 'We were told to split the adverse event for atrial flutter/atrial fibrillation. These are two different heart rhythms... they are not duplicate entries. ' (Site from DM).	Haylee Rowe (b) (4) (b) (4)	06 Apr 2021 21:17:40
User opened query 'Per DM CLR: Please review if this event is a duplicate of AE#1. If so, please delete entry. Else, review dates so there are no overlapping dates or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 06:56:43
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Apr 2021 17:54:34
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Apr 2021 17:54:34
User signature succeeded.	Priyantha Wijewardane (b) (4)	27 Mar 2021 14:58:05
Data point term sent to Coder	System	26 Mar 2021 20:31:11
User entered 'SIMULTANEOUS OCCURRENCE OF ATRIAL FIBRILLATION'	Haylee Rowe (b) (4) (b) (4)	26 Mar 2021 20:31:06

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US3752259
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:47:59
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:17:30
User signature succeeded.	Priyantha Wijewardane (b) (4)	27 Mar 2021 14:58:05
User entered 'Yes (Y)'	Haylee Rowe (b) (4) (b) (4)	26 Mar 2021 20:31:06

US3752259
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:47:59
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:17:30
User signature succeeded.	Priyantha Wijewardane (b) (4)	27 Mar 2021 14:58:05
User entered 'No (N)'	Haylee Rowe (b) (4) (b) (4)	26 Mar 2021 20:31:06

US3752259
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:47:59
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:17:30
User signature succeeded.	Priyantha Wijewardane (b) (4)	27 Mar 2021 14:58:05
User entered 'No (N)'	Haylee Rowe (b) (4) (b) (4)	26 Mar 2021 20:31:06

US3752259
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:47:59
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:17:30
User signature succeeded.	Priyantha Wijewardane (b) (4)	27 Mar 2021 14:58:05
User entered '20 Dec 2020'	Haylee Rowe (b) (4) (b) (4)	26 Mar 2021 20:31:06

US3752259
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:47:59
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:17:30
User signature succeeded.	Priyantha Wijewardane (b) (4)	27 Mar 2021 14:58:05
User entered empty.	Haylee Rowe (b) (4) (b) (4)	26 Mar 2021 20:31:06

US3752259
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:47:59
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	26 Mar 2021 20:31:06

US3752259
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:47:59
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:17:30
User signature succeeded.	Priyantha Wijewardane (b) (4)	27 Mar 2021 14:58:05
User entered 'No (N)'	Haylee Rowe (b) (4) (b) (4)	26 Mar 2021 20:31:06

US3752259
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:47:59
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:17:30
User signature succeeded.	Priyantha Wijewardane (b) (4)	27 Mar 2021 14:58:05
User entered '21 Dec 2020'	Haylee Rowe (b) (4) (b) (4)	26 Mar 2021 20:31:06

US3752259
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:47:59
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:17:30
User signature succeeded.	Priyantha Wijewardane (b) (4)	27 Mar 2021 14:58:05
User entered empty.	Haylee Rowe (b) (4) (b) (4)	26 Mar 2021 20:31:06

US3752259
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:47:59
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	26 Mar 2021 20:31:06

US3752259
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:47:59
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:17:30
User signature succeeded.	Priyantha Wijewardane (b) (4)	27 Mar 2021 14:58:05
User entered 'Grade 4 (Grade 4)'	Haylee Rowe (b) (4) (b) (4)	26 Mar 2021 20:31:06

US3752259
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:47:59
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:17:30
User signature succeeded.	Priyantha Wijewardane (b) (4)	27 Mar 2021 14:58:05
User entered 'Yes (Y)'	Haylee Rowe (b) (4) (b) (4)	26 Mar 2021 20:31:06

US3752259
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:47:59
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:17:30
User signature succeeded.	Priyantha Wijewardane (b) (4)	27 Mar 2021 14:58:05
User entered '0'	Haylee Rowe (b) (4) (b) (4)	26 Mar 2021 20:31:06

US3752259
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:47:59
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:17:30
User signature succeeded.	Priyantha Wijewardane (b) (4)	27 Mar 2021 14:58:05
User entered '0'	Haylee Rowe (b) (4) (b) (4)	26 Mar 2021 20:31:06

US3752259
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:47:59
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:17:30
User signature succeeded.	Priyantha Wijewardane (b) (4)	27 Mar 2021 14:58:05
User entered '1'	Haylee Rowe (b) (4) (b) (4)	26 Mar 2021 20:31:06

US3752259
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:47:59
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:17:30
User signature succeeded.	Priyantha Wijewardane (b) (4)	27 Mar 2021 14:58:05
User entered '20 Dec 2020'	Haylee Rowe (b) (4) (b) (4)	26 Mar 2021 20:31:06

US3752259
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:47:59
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:17:30
User signature succeeded.	Priyantha Wijewardane (b) (4)	27 Mar 2021 14:58:05
User entered '21 Dec 2020'	Haylee Rowe (b) (4) (b) (4)	26 Mar 2021 20:31:06

US3752259
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:47:59
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:17:30
User signature succeeded.	Priyantha Wijewardane (b) (4)	27 Mar 2021 14:58:05
User entered 'No (N)'	Haylee Rowe (b) (4) (b) (4)	26 Mar 2021 20:31:06

US3752259
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:47:59
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:17:30
User signature succeeded.	Priyantha Wijewardane (b) (4)	27 Mar 2021 14:58:05
User entered empty.	Haylee Rowe (b) (4) (b) (4)	26 Mar 2021 20:31:06

US3752259
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:47:59
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:17:30
User signature succeeded.	Priyantha Wijewardane (b) (4)	27 Mar 2021 14:58:05
User entered '0'	Haylee Rowe (b) (4) (b) (4)	26 Mar 2021 20:31:06

US3752259
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:47:59
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:17:30
User signature succeeded.	Priyantha Wijewardane (b) (4)	27 Mar 2021 14:58:05
User entered '0'	Haylee Rowe (b) (4) (b) (4)	26 Mar 2021 20:31:06

US3752259
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:47:59
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:17:30
User signature succeeded.	Priyantha Wijewardane (b) (4)	27 Mar 2021 14:58:05
User entered '0'	Haylee Rowe (b) (4) (b) (4)	26 Mar 2021 20:31:06

US3752259
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:47:59
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:17:30
User signature succeeded.	Priyantha Wijewardane (b) (4)	27 Mar 2021 14:58:05
User entered 'Not Related (NOT RELATED)'	Haylee Rowe (b) (4) (b) (4)	26 Mar 2021 20:31:06

US3752259
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:47:59
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:17:30
User signature succeeded.	Priyantha Wijewardane (b) (4)	27 Mar 2021 14:58:05
User entered 'Not Related (NOT RELATED)'	Haylee Rowe (b) (4) (b) (4)	26 Mar 2021 20:31:06

US3752259
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:47:59
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:17:30
User signature succeeded.	Priyantha Wijewardane (b) (4)	27 Mar 2021 14:58:05
User entered 'Not Applicable (NOT APPLICABLE)'	Haylee Rowe (b) (4) (b) (4)	26 Mar 2021 20:31:06

US3752259
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:47:59
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:17:30
User signature succeeded.	Priyantha Wijewardane (b) (4)	27 Mar 2021 14:58:05
User entered '0'	Haylee Rowe (b) (4) (b) (4)	26 Mar 2021 20:31:06

US3752259
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:47:59
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:17:30
User signature succeeded.	Priyantha Wijewardane (b) (4)	27 Mar 2021 14:58:05
User entered '1'	Haylee Rowe (b) (4) (b) (4)	26 Mar 2021 20:31:06

US3752259
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:47:59
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:17:30
User signature succeeded.	Priyantha Wijewardane (b) (4)	27 Mar 2021 14:58:05
User entered '1'	Haylee Rowe (b) (4) (b) (4)	26 Mar 2021 20:31:06

US3752259
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:47:59
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:17:30
User signature succeeded.	Priyantha Wijewardane (b) (4)	27 Mar 2021 14:58:05
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Haylee Rowe (b) (4) (b) (4)	26 Mar 2021 20:31:06

FDA-CBER-2022-1614-3181892

US3752259
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:47:59
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 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:17:30
User signature succeeded.	Priyantha Wijewardane (b) (4)	27 Mar 2021 14:58:05
User entered empty.	Haylee Rowe (b) (4) (b) (4)	26 Mar 2021 20:31:06

US3752259
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:47:59
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:17:30
User signature succeeded.	Priyantha Wijewardane	27 Mar 2021 14:58:05
User entered 'ADMITTED 20DEC2020WITH NEW ONSET A.FLUTTER. S/P CARDIOVERSION 21DEC2020. D/C HOME ON 21DEC2020. ASYMPTOMATIC AT DOSING.'	Haylee Rowe (b) (4) (b) (4)	26 Mar 2021 20:31:06

FDA-CBER-2022-1614-3181894

US3752259
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:47:59
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '1'	System	26 Mar 2021 20:31:06

US3752259
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:47:59
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '1'	System	26 Mar 2021 20:31:06

US3752259
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 09:47:59
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '0'	System	26 Mar 2021 20:31:06

FDA-CBER-2022-1614-3181897

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Generated On: 10 Jun 2021 09:47:59
Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:58:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 15:19:09

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:47:59
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Feb 2021 23:38:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Feb 2021 23:38:40
Data point term sent to Coder	System	01 Feb 2021 17:03:18
Coding entries removed.	Jamie Pettus (b) (4) (b) (4)	01 Feb 2021 17:02:33
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 16:01:34
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 22:46:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 22:46:33
Data point term sent to Coder	System	26 Oct 2020 14:39:37
Coding entries removed.	(b) (4), (b) (6)	26 Oct 2020 14:39:31
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:26:19

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:47:59
Name of Medication

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:26:19
Data point term sent to Coder	System	27 Aug 2020 15:20:18
User entered 'Meloxicam'	(b) (4), (b) (6)	27 Aug 2020 15:19:50

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:47:59
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User closed query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 03:18:37
Query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' answered with 'data updated' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	01 Feb 2021 17:02:54
User entered 'No (N)' reason for change: Data Entry Error	Jamie Pettus (b) (4) (b) (4)	01 Feb 2021 17:02:42
DataPoint Un-verified.	Jamie Pettus (b) (4) (b) (4)	01 Feb 2021 17:02:33
User entered 'Yes (Y)' reason for change: Data Entry Error	Jamie Pettus (b) (4) (b) (4)	01 Feb 2021 17:02:33
User opened query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 01:54:02
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 16:01:36
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 15:19:50

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:47:59
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
DataPoint Un-verified.	Jamie Pettus (b) (4) (b) (4)	01 Feb 2021 17:02:33
User entered 'OSTEOARTHRITIS (upper and lower extremities)' reason for change: Data Entry Error	Jamie Pettus (b) (4) (b) (4)	01 Feb 2021 17:02:33
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 16:02:39
User closed query 'Per DM CLR: Please specify the location and/or type of Arthritis. Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 18:17:35
Query 'Per DM CLR: Please specify the location and/or type of Arthritis. Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 14:39:39
User entered 'Osteoarthritis (unknown site)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Oct 2020 14:39:31
User opened query 'Per DM CLR: Please specify the location and/or type of Arthritis. Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 15:05:07
User entered 'Arthritis'	(b) (4), (b) (6)	27 Aug 2020 15:19:50

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:47:59
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:02:44
User entered '15'	(b) (4), (b) (6)	27 Aug 2020 15:19:50

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:47:59
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:02:46
User entered 'mg (mg)'	(b) (4), (b) (6)	27 Aug 2020 15:19:50

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:47:59
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:02:48
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:19:50

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:47:59
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:02:50
User entered 'once daily (QD)'	(b) (4), (b) (6)	27 Aug 2020 15:19:50

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:47:59
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:02:53
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:19:50

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US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:47:59
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:02:55
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	27 Aug 2020 15:19:50

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:47:59
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:02:56
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:19:50

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:47:59
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:02:59
User entered 'un UNK 2019'	(b) (4), (b) (6)	27 Aug 2020 15:19:50

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:47:59
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:03:02
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 15:19:50

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:47:59
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:03:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 15:19:50

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:47:59
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:03:09
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:19:50

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:47:59
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:03:12
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 15:19:50

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:47:59
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '1'	System	27 Aug 2020 15:19:50

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:47:59
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '1'	System	27 Aug 2020 15:19:50

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 09:47:59
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '804 (804)'	System	27 Aug 2020 15:19:50

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:47:59
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:03:27
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:26:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:26:24
Data point term sent to Coder	System	27 Aug 2020 15:21:20
User entered 'Metoprolol'	(b) (4), (b) (6)	27 Aug 2020 15:20:22

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:47:59
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:03:29
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 15:20:22

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:47:59
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:03:32
User entered 'HYPERTENSION' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Aug 2020 15:20:37
User entered 'Hypetension'	(b) (4), (b) (6)	27 Aug 2020 15:20:22

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:47:59
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:03:35
User entered '100'	(b) (4), (b) (6)	27 Aug 2020 15:20:22

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:47:59
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:03:37
User entered 'mg (mg)'	(b) (4), (b) (6)	27 Aug 2020 15:20:22

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:47:59
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:03:40
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:20:22

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:47:59
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:03:43
User entered 'once daily (QD)'	(b) (4), (b) (6)	27 Aug 2020 15:20:22

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:47:59
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:03:44
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:20:22

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:47:59
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:03:47
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	27 Aug 2020 15:20:22

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:47:59
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:03:50
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:20:22

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:47:59
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:03:52
User entered 'un UNK 2019'	(b) (4), (b) (6)	27 Aug 2020 15:20:22

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:47:59
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:03:54
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 15:20:22

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:47:59
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:13:04
User closed query 'please verify as 21Dec as per CM log' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 17:13:02
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Mar 2021 16:22:02
Query 'please verify as 21Dec as per CM log' answered with 'updated' (Site from CRA).	Jamie Pettus (b) (4) (b) (4)	10 Mar 2021 19:09:28
Signature has been broken.	Jamie Pettus (b) (4) (b) (4)	10 Mar 2021 19:09:21
User entered 'No (N)' reason for change: Data Entry Error	Jamie Pettus (b) (4) (b) (4)	10 Mar 2021 19:09:21
User opened query 'please verify as 21Dec as per CM log' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 21:16:59
DataPoint Un-verified.	(b) (4), (b) (6)	08 Mar 2021 21:16:30
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 16:03:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 15:20:22

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US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:47:59
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:13:06
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:22:02
Signature has been broken.	Jamie Pettus (b) (4) (b) (4)	10 Mar 2021 19:09:21
User entered '21 Dec 2020' reason for change: Data Entry Error	Jamie Pettus (b) (4) (b) (4)	10 Mar 2021 19:09:21
DataPoint Un-verified.	(b) (4), (b) (6)	08 Mar 2021 21:16:32
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:03:59
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:20:22

FDA-CBER-2022-1614-3181931

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:47:59
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:04:01
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 15:20:22

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:47:59
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '1'	System	27 Aug 2020 15:20:22

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:47:59
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '1'	System	27 Aug 2020 15:20:22

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 09:47:59
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '804 (804)'	System	27 Aug 2020 15:20:22

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:47:59
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:04:16
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: SIMVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:26:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:26:24
Data point term sent to Coder	System	27 Aug 2020 15:21:21
User entered 'Simvastatin'	(b) (4), (b) (6)	27 Aug 2020 15:21:20

FDA-CBER-2022-1614-3181936

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:47:59
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:04:17
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 15:21:20

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:47:59
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:04:20
User entered 'Hypercholesterolemia'	(b) (4), (b) (6)	27 Aug 2020 15:21:20

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:47:59
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:04:24
User entered '40'	(b) (4), (b) (6)	27 Aug 2020 15:21:20

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:47:59
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:04:26
User entered 'mg (mg)'	(b) (4), (b) (6)	27 Aug 2020 15:21:20

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:47:59
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:04:28
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:21:20

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:47:59
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:04:29
User entered 'once daily (QD)'	(b) (4), (b) (6)	27 Aug 2020 15:21:20

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:47:59
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:04:32
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:21:20

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:47:59
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:04:34
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	27 Aug 2020 15:21:20

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:47:59
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:04:35
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:21:20

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:47:59
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:04:39
User entered 'un UNK 2019'	(b) (4), (b) (6)	27 Aug 2020 15:21:20

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:47:59
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:04:41
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 15:21:20

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:47:59
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:13:31
User closed query 'please verify as 21Dec20 as per CM log' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 17:13:30
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Mar 2021 16:22:02
Query 'please verify as 21Dec20 as per CM log' answered with 'updated' (Site from CRA).	Jamie Pettus (b) (4) (b) (4)	10 Mar 2021 19:10:10
Signature has been broken.	Jamie Pettus (b) (4) (b) (4)	10 Mar 2021 19:09:53
User entered 'No (N)' reason for change: Data Entry Error	Jamie Pettus (b) (4) (b) (4)	10 Mar 2021 19:09:53
User opened query 'please verify as 21Dec20 as per CM log' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 21:17:37
DataPoint Un-verified.	(b) (4), (b) (6)	08 Mar 2021 21:17:14
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 16:04:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 15:21:20

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US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:47:59
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:13:33
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:22:02
Signature has been broken.	Jamie Pettus (b) (4)	10 Mar 2021 19:09:53
User entered '21 Dec 2020' reason for change: Data Entry Error	Jamie Pettus (b) (4)	10 Mar 2021 19:09:53
DataPoint Un-verified.	(b) (4), (b) (6)	08 Mar 2021 21:17:15
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 16:04:47
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:21:20

FDA-CBER-2022-1614-3181949

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:47:59
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:04:49
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 15:21:20

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:47:59
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '1'	System	27 Aug 2020 15:21:20

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:47:59
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '1'	System	27 Aug 2020 15:21:20

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US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 09:47:59
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '804 (804)'	System	27 Aug 2020 15:21:20

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:47:59
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:05:47
User closed query 'Per MM, please review and confirm as this medication meet EC # 12 'Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening (for corticosteroids ≥ 20 mg/day of prednisone equivalent)' and Please raise a PD accordingly. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 20:09:23
Query 'Per MM, please review and confirm as this medication meet EC # 12 'Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening (for corticosteroids ≥ 20 mg/day of prednisone equivalent)' and Please raise a PD accordingly. ' answered with 'subject randomized in error. subject has taken mesalamine longer than > 14 days' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 20:15:28
User opened query 'Per MM, please review and confirm as this medication meet EC # 12 'Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening (for corticosteroids ≥ 20 mg/day of prednisone equivalent)' and Please raise a PD accordingly. ' (Site from DM).	(b) (4), (b) (6)	18 Oct 2020 20:09:48
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, ATC: INTESTINAL ANTIINFLAMMATORY AGENTS, ATC: AMINOSALICYLIC ACID AND SIMILAR AGENTS, PRODUCT: MESALAZINE, PRODUCTSYNONYM: MESALAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:26:56

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:47:59
Name of Medication

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:26:56
Data point term sent to Coder	System	27 Aug 2020 15:22:22
User entered 'Mesalamine'	(b) (4), (b) (6)	27 Aug 2020 15:22:12

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:47:59
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:05:57
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 15:22:12

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:47:59
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:06:00
User entered 'Ulcerative colitis'	(b) (4), (b) (6)	27 Aug 2020 15:22:12

FDA-CBER-2022-1614-3181957

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:47:59
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:06:10
User entered '1.2'	(b) (4), (b) (6)	27 Aug 2020 15:22:12

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:47:59
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:06:11
User entered 'g (g)'	(b) (4), (b) (6)	27 Aug 2020 15:22:12

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:47:59
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:06:13
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:22:12

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:47:59
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:06:14
User entered 'once daily (QD)'	(b) (4), (b) (6)	27 Aug 2020 15:22:12

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:47:59
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:06:18
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:22:12

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:47:59
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:06:20
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	27 Aug 2020 15:22:12

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:47:59
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:06:21
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:22:12

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:47:59
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:06:27
User entered 'un UNK 2020'	(b) (4), (b) (6)	27 Aug 2020 15:22:12

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:47:59
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:06:28
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 15:22:12

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:47:59
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:06:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 15:22:12

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:47:59
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:06:33
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:22:12

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:47:59
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:06:36
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 15:22:12

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:47:59
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '1'	System	27 Aug 2020 15:22:12

FDA-CBER-2022-1614-3181970

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:47:59
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '1'	System	27 Aug 2020 15:22:12

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 09:47:59
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '804 (804)'	System	27 Aug 2020 15:22:12

FDA-CBER-2022-1614-3181972

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:47:59
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
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)	02 Dec 2020 16:16:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Dec 2020 16:16:49
Data point term sent to Coder	System	02 Dec 2020 16:16:22
Coding entries removed.	Haylee Rowe (b) (4) (b) (4)	02 Dec 2020 16:15:26
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 16:06:50
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)	27 Aug 2020 19:26:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:26:37
Data point term sent to Coder	System	27 Aug 2020 15:23:23
User entered 'Multivitamin'	(b) (4), (b) (6)	27 Aug 2020 15:22:55

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:47:59
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:06:54
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Oct 2020 18:51:11
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 15:22:55

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:47:59
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User closed query 'Source says general health--please update EDC or clarify.' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 17:13:19
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
Query 'Source says general health--please update EDC or clarify.' answered with 'UPDATED THE SOURCE ' (Site from CRA).	Haylee Rowe (b) (4) (b) (4)	02 Dec 2020 16:15:41
User entered 'GENERAL HEALTH SUPPLEMENT' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	02 Dec 2020 16:15:26
User opened query 'Source says general health--please update EDC or clarify.' (Site from CRA).	(b) (4), (b) (6)	01 Dec 2020 16:07:39
User entered 'Supplement'	(b) (4), (b) (6)	27 Aug 2020 15:22:55

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:47:59
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:07:48
User entered '1'	(b) (4), (b) (6)	27 Aug 2020 15:22:55

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:47:59
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:07:51
User entered 'capsule (CAPSULE)'	(b) (4), (b) (6)	27 Aug 2020 15:22:55

FDA-CBER-2022-1614-3181977

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:47:59
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:08:10
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:22:55

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:47:59
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:08:13
User entered 'once daily (QD)'	(b) (4), (b) (6)	27 Aug 2020 15:22:55

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:47:59
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:08:15
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:22:55

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:47:59
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:08:17
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	27 Aug 2020 15:22:55

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:47:59
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:08:23
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:22:55

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:47:59
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:08:37
User entered 'un UNK 2010'	(b) (4), (b) (6)	27 Aug 2020 15:22:55

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:47:59
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:08:39
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 15:22:55

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:47:59
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:08:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 15:22:55

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:47:59
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:08:45
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:22:55

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:47:59
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:08:47
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 15:22:55

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:47:59
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '1'	System	27 Aug 2020 15:22:55

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US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:47:59
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '1'	System	27 Aug 2020 15:22:55

FDA-CBER-2022-1614-3181989

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 09:47:59
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '804 (804)'	System	27 Aug 2020 15:22:55

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:47:59
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Dec 2020 16:19:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Dec 2020 16:19:18
Data point term sent to Coder	System	02 Dec 2020 16:17:22
Coding entries removed.	Haylee Rowe (b) (4) (b) (4)	02 Dec 2020 16:16:30
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 16:09:06
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:26:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:26:52
Data point term sent to Coder	System	27 Aug 2020 15:24:25
User entered 'Aspirin'	(b) (4), (b) (6)	27 Aug 2020 15:23:34

FDA-CBER-2022-1614-3181991

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:47:59
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:09:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 15:23:34

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:47:59
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 20:39:42
User closed query 'Source says heart health--please correct EDC or source as applicable.' (Site from CRA).	(b) (4), (b) (6)	24 Feb 2021 20:39:37
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
Query 'Source says heart health--please correct EDC or source as applicable.' answered with 'CORRECTED EDC' (Site from CRA).	Haylee Rowe (b) (4) (b) (4)	02 Dec 2020 16:16:37
User entered 'HEART HEALTH' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	02 Dec 2020 16:16:30
User opened query 'Source says heart health--please correct EDC or source as applicable.' (Site from CRA).	(b) (4), (b) (6)	01 Dec 2020 16:09:35
User entered 'Prophylaxis for cardiac disease'	(b) (4), (b) (6)	27 Aug 2020 15:23:34

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:47:59
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:09:42
User entered '81'	(b) (4), (b) (6)	27 Aug 2020 15:23:34

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:47:59
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:09:44
User entered 'mg (mg)'	(b) (4), (b) (6)	27 Aug 2020 15:23:34

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:47:59
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:09:45
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:23:34

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:47:59
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:09:47
User entered 'once daily (QD)'	(b) (4), (b) (6)	27 Aug 2020 15:23:34

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:47:59
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:09:49
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:23:34

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:47:59
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:09:51
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	27 Aug 2020 15:23:34

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:47:59
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:09:52
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:23:34

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:47:59
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:09:56
User entered 'un UNK 2010'	(b) (4), (b) (6)	27 Aug 2020 15:23:34

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:47:59
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:09:59
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 15:23:34

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:47:59
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:13:46
User closed query 'please verify as 21Dec20 per CM log' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 17:13:45
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Mar 2021 16:22:02
Query 'please verify as 21Dec20 per CM log' answered with 'updated' (Site from CRA).	Jamie Pettus (b) (4) (b) (4)	10 Mar 2021 19:08:46
Signature has been broken.	Jamie Pettus (b) (4) (b) (4)	10 Mar 2021 19:08:33
User entered 'No (N)' reason for change: Data Entry Error	Jamie Pettus (b) (4) (b) (4)	10 Mar 2021 19:08:33
User opened query 'please verify as 21Dec20 per CM log' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 21:16:07
DataPoint Un-verified.	(b) (4), (b) (6)	08 Mar 2021 21:15:38
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 16:10:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 15:23:34

FDA-CBER-2022-1614-3182003

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:47:59
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 17:13:49
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:22:02
Signature has been broken.	Jamie Pettus (b) (4) (b) (4)	10 Mar 2021 19:08:33
User entered '21 Dec 2020' reason for change: Data Entry Error	Jamie Pettus (b) (4) (b) (4)	10 Mar 2021 19:08:33
DataPoint Un-verified.	(b) (4), (b) (6)	08 Mar 2021 21:15:44
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:10:03
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:23:34

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:47:59
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:10:05
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 15:23:34

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:47:59
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '1'	System	27 Aug 2020 15:23:34

FDA-CBER-2022-1614-3182006

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:47:59
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '1'	System	27 Aug 2020 15:23:34

FDA-CBER-2022-1614-3182007

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 09:47:59
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '804 (804)'	System	27 Aug 2020 15:23:34

FDA-CBER-2022-1614-3182008

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:47:59
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Dec 2020 16:19:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Dec 2020 16:19:53
Data point term sent to Coder	System	02 Dec 2020 16:19:23
Coding entries removed.	Haylee Rowe (b) (4) (b) (4)	02 Dec 2020 16:18:30
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 16:11:33
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:26:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:26:50
Data point term sent to Coder	System	27 Aug 2020 15:24:26
User entered 'Magnesium'	(b) (4), (b) (6)	27 Aug 2020 15:24:05

FDA-CBER-2022-1614-3182009

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:47:59
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:11:37
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Oct 2020 18:51:32
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 15:24:05

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:47:59
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User closed query 'Source says heart health--please update EDC or source as applicable.' (Site from CRA).	(b) (4), (b) (6)	24 Feb 2021 20:44:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
Query 'Source says heart health--please update EDC or source as applicable.' answered with 'UPDATED EDC' (Site from CRA).	Haylee Rowe (b) (4) (b) (4)	02 Dec 2020 16:18:39
User entered 'HEART HEALTH' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	02 Dec 2020 16:18:30
User opened query 'Source says heart health--please update EDC or source as applicable.' (Site from CRA).	(b) (4), (b) (6)	01 Dec 2020 16:12:04
User entered 'Supplement'	(b) (4), (b) (6)	27 Aug 2020 15:24:05

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:47:59
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:12:10
User entered '250'	(b) (4), (b) (6)	27 Aug 2020 15:24:05

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:47:59
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:12:12
User entered 'mg (mg)'	(b) (4), (b) (6)	27 Aug 2020 15:24:05

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:47:59
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:12:13
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:24:05

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:47:59
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:12:16
User entered 'once daily (QD)'	(b) (4), (b) (6)	27 Aug 2020 15:24:05

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:47:59
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:12:18
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:24:05

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:47:59
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:12:20
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	27 Aug 2020 15:24:05

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:47:59
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:12:24
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:24:05

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:47:59
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:12:27
User entered 'un UNK 2010'	(b) (4), (b) (6)	27 Aug 2020 15:24:05

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:47:59
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:12:30
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 15:24:05

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:47:59
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:12:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 15:24:05

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:47:59
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:12:34
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:24:05

FDA-CBER-2022-1614-3182022

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:47:59
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:12:36
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 15:24:05

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:47:59
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '1'	System	27 Aug 2020 15:24:05

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:47:59
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '1'	System	27 Aug 2020 15:24:05

FDA-CBER-2022-1614-3182025

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 09:47:59
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '804 (804)'	System	27 Aug 2020 15:24:05

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:47:59
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: SILYBUM MARIANUM, PRODUCTSYNONYM: MILK THISTLE [SILYBUM MARIANUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Dec 2020 16:19:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Dec 2020 16:19:52
Data point term sent to Coder	System	02 Dec 2020 16:19:23
Coding entries removed.	Haylee Rowe (b) (4) (b) (4)	02 Dec 2020 16:19:01
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 16:12:49
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: SILYBUM MARIANUM, PRODUCTSYNONYM: MILK THISTLE [SILYBUM MARIANUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Nov 2020 13:47:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Nov 2020 13:47:12
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: SILYBUM MARIANUM HERB - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:27:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:27:00
Data point term sent to Coder	System	27 Aug 2020 15:25:27
User entered 'Milk thistle'	(b) (4), (b) (6)	27 Aug 2020 15:24:50

FDA-CBER-2022-1614-3182027

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:47:59
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:12:52
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 13:36:59
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 15:24:50

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:47:59
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User closed query 'Source say liver health--please update EDC or source as applicable.' (Site from CRA).	(b) (4), (b) (6)	24 Feb 2021 20:45:05
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
Query 'Source say liver health--please update EDC or source as applicable.' answered with 'UPDATED EDC' (Site from CRA).	Haylee Rowe (b) (4) (b) (4)	02 Dec 2020 16:19:10
User entered 'LIVER HEALTH' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	02 Dec 2020 16:19:01
User opened query 'Source say liver health--please update EDC or source as applicable.' (Site from CRA).	(b) (4), (b) (6)	01 Dec 2020 16:13:16
User entered 'Supplement'	(b) (4), (b) (6)	27 Aug 2020 15:24:50

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:47:59
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:13:21
User entered '240'	(b) (4), (b) (6)	27 Aug 2020 15:24:50

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:47:59
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:13:22
User entered 'mg (mg)'	(b) (4), (b) (6)	27 Aug 2020 15:24:50

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:47:59
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:13:23
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:24:50

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:47:59
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:13:27
User entered 'twice daily (BID)'	(b) (4), (b) (6)	27 Aug 2020 15:24:50

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:47:59
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:13:30
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:24:50

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:47:59
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:13:32
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	27 Aug 2020 15:24:50

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:47:59
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:13:33
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:24:50

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:47:59
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:13:39
User entered 'un UNK 2010'	(b) (4), (b) (6)	27 Aug 2020 15:24:50

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:47:59
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:13:41
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 15:24:50

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:47:59
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:13:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 15:24:50

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:47:59
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:13:47
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:24:50

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:47:59
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:13:49
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 15:24:50

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:47:59
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '2'	System	27 Aug 2020 15:24:50

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:47:59
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '1'	System	27 Aug 2020 15:24:50

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 09:47:59
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '804 (804)'	System	27 Aug 2020 15:24:50

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:47:59
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 16:14:11
DataPoint Un-verified.	(b) (4), (b) (6)	01 Dec 2020 16:14:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 16:14:05
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B1, PLAIN AND IN COMBINATION WITH VITAMIN B6 AND B12, ATC: VITAMIN B1, PLAIN, PRODUCT: THIAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 21:55:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 21:55:12
Data point term sent to Coder	System	27 Aug 2020 15:26:28
User entered 'All Thiamine'	(b) (4), (b) (6)	27 Aug 2020 15:25:32

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US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:47:59
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:14:13
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 13:37:08
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 15:25:32

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:47:59
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:14:15
User entered 'Supplement'	(b) (4), (b) (6)	27 Aug 2020 15:25:32

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US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:47:59
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:14:17
User entered '50'	(b) (4), (b) (6)	27 Aug 2020 15:25:32

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:47:59
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:14:19
User entered 'mg (mg)'	(b) (4), (b) (6)	27 Aug 2020 15:25:32

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:47:59
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:14:21
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:25:32

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:47:59
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:14:24
User entered 'once daily (QD)'	(b) (4), (b) (6)	27 Aug 2020 15:25:32

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:47:59
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:14:25
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:25:32

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:47:59
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:14:28
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	27 Aug 2020 15:25:32

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:47:59
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:14:29
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:25:32

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:47:59
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:14:33
User entered 'un UNK 2010'	(b) (4), (b) (6)	27 Aug 2020 15:25:32

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:47:59
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:14:35
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 15:25:32

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:47:59
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:14:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 15:25:32

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:47:59
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:14:39
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:25:32

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US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:47:59
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:14:40
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 15:25:32

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:47:59
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '1'	System	27 Aug 2020 15:25:32

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:47:59
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '1'	System	27 Aug 2020 15:25:32

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US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 09:47:59
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '804 (804)'	System	27 Aug 2020 15:25:32

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:47:59
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:15:00
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, PRODUCT: ASCORBIC ACID;BETACAROTENE;CUPRIC OXIDE;TOCOPHERYL ACETATE;ZINC OXIDE, PRODUCTSYNONYM: PRESERVISION - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Nov 2020 04:48:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Nov 2020 04:48:54
Data point term sent to Coder	System	27 Oct 2020 14:54:17
Coding entries removed.	(b) (4), (b) (6)	27 Oct 2020 14:53:29
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, PRODUCT: ASCORBIC ACID;BETACAROTENE;CUPRIC OXIDE;TOCOPHERYL ACETATE;ZINC OXIDE, PRODUCTSYNONYM: PRESERVISION - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 12:15:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 12:15:42
Data point term sent to Coder	System	27 Aug 2020 15:27:32
User entered 'Preservision'	(b) (4), (b) (6)	27 Aug 2020 15:26:56

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:47:59
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:15:02
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 15:26:56

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:47:59
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:15:04
User entered 'Dry eyes'	(b) (4), (b) (6)	27 Aug 2020 15:26:56

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:47:59
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:15:16
User entered '2'	(b) (4), (b) (6)	27 Aug 2020 15:26:56

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US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:47:59
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:15:18
User entered 'Other (OTHER)'	(b) (4), (b) (6)	27 Aug 2020 15:26:56

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:47:59
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:15:19
User entered 'gtt'	(b) (4), (b) (6)	27 Aug 2020 15:26:56

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:47:59
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:15:22
User entered 'once daily (QD)'	(b) (4), (b) (6)	27 Aug 2020 15:26:56

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:47:59
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:15:23
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:26:56

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:47:59
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:15:33
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 17:51:26
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 14:53:35
User entered 'Topical (TOPICAL)' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 14:53:29
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 15:20:35
User entered 'Intraocular (INTRAOCULAR)'	(b) (4), (b) (6)	27 Aug 2020 15:26:56

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:47:59
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:15:38
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:26:56

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:47:59
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:15:40
User entered 'un UNK 2015'	(b) (4), (b) (6)	27 Aug 2020 15:26:56

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:47:59
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:15:42
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 15:26:56

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:47:59
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:15:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 15:26:56

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:47:59
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:15:46
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:26:56

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:47:59
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:15:49
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 15:26:56

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:47:59
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '1'	System	27 Aug 2020 15:26:56

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US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:47:59
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '1'	System	27 Aug 2020 15:26:56

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 10 Jun 2021 09:47:59
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '804 (804)'	System	27 Aug 2020 15:26:56

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:47:59
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:17:13
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: TIZANIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Nov 2020 03:58:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Nov 2020 03:58:53
Data point term sent to Coder	System	29 Oct 2020 18:55:16
Coding entries removed.	(b) (4), (b) (6)	29 Oct 2020 18:54:22
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: TIZANIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 00:48:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 00:48:57
Data point term sent to Coder	System	27 Aug 2020 15:28:34
User entered 'Tizanidine'	(b) (4), (b) (6)	27 Aug 2020 15:27:36

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:47:59
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:17:11
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 15:27:36

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:47:59
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:17:14
User entered 'MUSCLE RELAXANT for muscle spasms' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Oct 2020 18:54:22
User entered 'Muscle relaxant'	(b) (4), (b) (6)	27 Aug 2020 15:27:36

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:47:59
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:17:17
User entered '2'	(b) (4), (b) (6)	27 Aug 2020 15:27:36

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:47:59
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:17:20
User entered 'mg (mg)'	(b) (4), (b) (6)	27 Aug 2020 15:27:36

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:47:59
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:17:22
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:27:36

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US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:47:59
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:17:23
User entered 'three times daily (TID)'	(b) (4), (b) (6)	27 Aug 2020 15:27:36

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:47:59
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:17:26
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:27:36

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:47:59
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:17:27
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	27 Aug 2020 15:27:36

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:47:59
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:17:29
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:27:36

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:47:59
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:17:32
User entered 'un UNK 2017'	(b) (4), (b) (6)	27 Aug 2020 15:27:36

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:47:59
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:17:35
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 15:27:36

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:47:59
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:17:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 15:27:36

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:47:59
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:17:38
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:27:36

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US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:47:59
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:17:41
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 15:27:36

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:47:59
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '3'	System	27 Aug 2020 15:27:36

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:47:59
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '1'	System	27 Aug 2020 15:27:36

FDA-CBER-2022-1614-3182097

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 10 Jun 2021 09:47:59
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '804 (804)'	System	27 Aug 2020 15:27:36

FDA-CBER-2022-1614-3182098

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:47:59
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:17:51
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)	29 Oct 2020 18:53:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 18:53:45
Data point term sent to Coder	System	29 Oct 2020 18:53:12
User entered 'Seasonal influenza vaccine'	(b) (4), (b) (6)	29 Oct 2020 18:53:04

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:47:59
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:18:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Oct 2020 18:53:04

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:47:59
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:18:38
User entered 'Prophylaxis for seasonal influenza'	(b) (4), (b) (6)	29 Oct 2020 18:53:04

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:47:59
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User closed query 'Source says 1 injection--please update EDC or source as applicable.' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 14:56:31
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
Query 'Source says 1 injection--please update EDC or source as applicable.' answered with 'Updated the source. ' (Site from CRA).	Haylee Rowe (b) (4) (b) (4)	02 Dec 2020 16:13:00
User opened query 'Source says 1 injection--please update EDC or source as applicable.' (Site from CRA).	(b) (4), (b) (6)	01 Dec 2020 16:19:39
DataPoint Un-verified.	(b) (4), (b) (6)	01 Dec 2020 16:18:49
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 16:18:40
User entered '0.5'	(b) (4), (b) (6)	29 Oct 2020 18:53:04

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:47:59
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 18:53:04

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:47:59
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:19:43
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 18:53:04

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:47:59
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:19:44
User entered 'once (ONCE)'	(b) (4), (b) (6)	29 Oct 2020 18:53:04

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:47:59
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:19:46
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 18:53:04

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:47:59
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:19:48
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	29 Oct 2020 18:53:04

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:47:59
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:19:51
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 18:53:04

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:47:59
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:19:57
User entered '14 Oct 2020'	(b) (4), (b) (6)	29 Oct 2020 18:53:04

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US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:47:59
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:19:59
User entered '0'	(b) (4), (b) (6)	29 Oct 2020 18:53:04

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:47:59
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:20:01
User entered 'No (N)'	(b) (4), (b) (6)	29 Oct 2020 18:53:04

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:47:59
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 16:20:09
DataPoint Un-verified.	(b) (4), (b) (6)	01 Dec 2020 16:20:07
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 16:20:03
User entered '14 Oct 2020'	(b) (4), (b) (6)	29 Oct 2020 18:53:04

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:47:59
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 16:20:10
User entered 'No (N)'	(b) (4), (b) (6)	29 Oct 2020 18:53:04

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:47:59
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	29 Oct 2020 18:53:04

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:47:59
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	29 Oct 2020 18:53:04

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 10 Jun 2021 09:47:59
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	29 Oct 2020 18:53:04

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:47:59
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: ANTIARRHYTHMICS, CLASS I AND III, ATC: ANTIARRHYTHMICS, CLASS III, PRODUCT: AMIODARONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Dec 2020 18:58:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Dec 2020 18:58:00
Data point term sent to Coder	System	22 Dec 2020 18:56:53
User entered 'Amiodarone'	Lauren Evans (b) (4)	22 Dec 2020 18:56:22

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:47:59
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'No (N)'	Lauren Evans (b) (4)	22 Dec 2020 18:56:22

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:47:59
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'atrial flutter'	Lauren Evans (b) (4)	22 Dec 2020 18:56:22

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:47:59
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered '200'	Lauren Evans (b) (4)	22 Dec 2020 18:56:22

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:47:59
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'mg (mg)'	Lauren Evans (b) (4)	22 Dec 2020 18:56:22

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:47:59
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered empty.	Lauren Evans (b) (4)	22 Dec 2020 18:56:22

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:47:59
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'once daily (QD)'	Lauren Evans (b) (4)	22 Dec 2020 18:56:22

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:47:59
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered empty.	Lauren Evans (b) (4)	22 Dec 2020 18:56:22

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:47:59
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'Oral (ORAL)'	Lauren Evans (b) (4)	22 Dec 2020 18:56:22

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:47:59
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered empty.	Lauren Evans (b) (4)	22 Dec 2020 18:56:22

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:47:59
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered '20 Dec 2020'	Lauren Evans (b) (4)	22 Dec 2020 18:56:22

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:47:59
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered '0'	Lauren Evans (b) (4)	22 Dec 2020 18:56:22

FDA-CBER-2022-1614-3182128

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:47:59
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 14:25:30
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' answered with 'the medication is the reason the AE resolved' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	25 Feb 2021 22:03:37
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	21 Feb 2021 13:17:49
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'Yes (Y)'	Lauren Evans (b) (4)	22 Dec 2020 18:56:22

FDA-CBER-2022-1614-3182129

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:47:59
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered empty.	Lauren Evans (b) (4)	22 Dec 2020 18:56:22

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:47:59
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User closed query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 11:07:20
Query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify. ' answered with 'data updated' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	01 Feb 2021 17:03:42
User entered 'No (N)' reason for change: Data Entry Error	Jamie Pettus (b) (4) (b) (4)	01 Feb 2021 17:03:33
User opened query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 08:43:50
User entered 'Yes (Y)'	Lauren Evans (b) (4)	22 Dec 2020 18:56:22

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:47:59
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '1'	System	22 Dec 2020 18:56:22

FDA-CBER-2022-1614-3182132

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:47:59
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '1'	System	22 Dec 2020 18:56:22

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 10 Jun 2021 09:47:59
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '804 (804)'	System	22 Dec 2020 18:56:22

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:47:59
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Dec 2020 19:11:53
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 Dec 2020 19:11:53
Data point term sent to Coder	System	22 Dec 2020 18:57:54
User entered 'apixaban'	Lauren Evans (b) (4)	22 Dec 2020 18:57:19

FDA-CBER-2022-1614-3182135

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:47:59
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'Yes (Y)'	Lauren Evans (b) (4)	22 Dec 2020 18:57:19

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:47:59
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'Stroke/blood clot prophylaxis'	Lauren Evans (b) (4)	22 Dec 2020 18:57:19

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:47:59
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered '5'	Lauren Evans (b) (4)	22 Dec 2020 18:57:19

FDA-CBER-2022-1614-3182138

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:47:59
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'mg (mg)'	Lauren Evans (b) (4)	22 Dec 2020 18:57:19

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:47:59
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered empty.	Lauren Evans (b) (4)	22 Dec 2020 18:57:19

FDA-CBER-2022-1614-3182140

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:47:59
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'twice daily (BID)'	Lauren Evans (b) (4)	22 Dec 2020 18:57:19

FDA-CBER-2022-1614-3182141

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:47:59
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered empty.	Lauren Evans (b) (4)	22 Dec 2020 18:57:19

FDA-CBER-2022-1614-3182142

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:47:59
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'Oral (ORAL)'	Lauren Evans (b) (4)	22 Dec 2020 18:57:19

FDA-CBER-2022-1614-3182143

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:47:59
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered empty.	Lauren Evans (b) (4)	22 Dec 2020 18:57:19

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:47:59
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered '20 Dec 2020'	Lauren Evans (b) (4)	22 Dec 2020 18:57:19

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:47:59
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered '0'	Lauren Evans (b) (4)	22 Dec 2020 18:57:19

FDA-CBER-2022-1614-3182146

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:47:59
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'Yes (Y)'	Lauren Evans (b) (4)	22 Dec 2020 18:57:19

FDA-CBER-2022-1614-3182147

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:47:59
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered empty.	Lauren Evans (b) (4)	22 Dec 2020 18:57:19

FDA-CBER-2022-1614-3182148

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:47:59
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User closed query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 11:07:26
Query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify. ' answered with 'data updated' (Site from DM).	Jamie Pettus (b) (4)	01 Feb 2021 17:04:06
User entered 'No (N)' reason for change: Data Entry Error	Jamie Pettus (b) (4)	01 Feb 2021 17:03:58
User opened query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 08:47:49
User entered 'Yes (Y)'	Lauren Evans (b) (4)	22 Dec 2020 18:57:19

FDA-CBER-2022-1614-3182149

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:47:59
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '2'	System	22 Dec 2020 18:57:19

FDA-CBER-2022-1614-3182150

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:47:59
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '1'	System	22 Dec 2020 18:57:19

FDA-CBER-2022-1614-3182151

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 10 Jun 2021 09:47:59
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '804 (804)'	System	22 Dec 2020 18:57:19

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:47:59
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening MIXED HYPERLIPIDEMIA should be recorded, and update con med indication or provide clarification.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 03:24:11
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening MIXED HYPERLIPIDEMIA should be recorded, and update con med indication or provide clarification.' answered with 'no AE needed per investigator' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	01 Feb 2021 17:05:47
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening MIXED HYPERLIPIDEMIA should be recorded, and update con med indication or provide clarification.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 08:48:15
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)	22 Dec 2020 19:00:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Dec 2020 19:00:51
Data point term sent to Coder	System	22 Dec 2020 18:59:56
User entered 'Atorvastatin'	Lauren Evans (b) (4)	22 Dec 2020 18:59:14

FDA-CBER-2022-1614-3182153

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:47:59
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'No (N)'	Lauren Evans (b) (4)	22 Dec 2020 18:59:14

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:47:59
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'mixed hyperlipidemia'	Lauren Evans (b) (4)	22 Dec 2020 18:59:14

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:47:59
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered '20'	Lauren Evans (b) (4)	22 Dec 2020 18:59:14

FDA-CBER-2022-1614-3182156

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:47:59
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'mg (mg)'	Lauren Evans (b) (4)	22 Dec 2020 18:59:14

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:47:59
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered empty.	Lauren Evans (b) (4)	22 Dec 2020 18:59:14

FDA-CBER-2022-1614-3182158

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:47:59
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'once daily (QD)'	Lauren Evans (b) (4)	22 Dec 2020 18:59:14

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:47:59
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered empty.	Lauren Evans (b) (4)	22 Dec 2020 18:59:14

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:47:59
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'Oral (ORAL)'	Lauren Evans (b) (4)	22 Dec 2020 18:59:14

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:47:59
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered empty.	Lauren Evans (b) (4)	22 Dec 2020 18:59:14

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:47:59
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered '20 Dec 2020'	Lauren Evans (b) (4)	22 Dec 2020 18:59:14

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:47:59
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered '0'	Lauren Evans (b) (4)	22 Dec 2020 18:59:14

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:47:59
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'Yes (Y)'	Lauren Evans (b) (4)	22 Dec 2020 18:59:14

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:47:59
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered empty.	Lauren Evans (b) (4)	22 Dec 2020 18:59:14

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:47:59
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User closed query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 03:24:20
Query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' answered with 'data updated' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	01 Feb 2021 17:06:00
User entered 'No (N)' reason for change: Data Entry Error	Jamie Pettus (b) (4) (b) (4)	01 Feb 2021 17:05:52
User opened query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 08:48:32
User entered 'Yes (Y)'	Lauren Evans (b) (4)	22 Dec 2020 18:59:14

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:47:59
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '1'	System	22 Dec 2020 18:59:14

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:47:59
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '1'	System	22 Dec 2020 18:59:14

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 10 Jun 2021 09:47:59
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '804 (804)'	System	22 Dec 2020 18:59:14

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US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:47:59
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Dec 2020 19:04:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Dec 2020 19:04:46
Data point term sent to Coder	System	22 Dec 2020 19:04:03
User entered 'cetirizine'	Lauren Evans (b) (4)	22 Dec 2020 19:03:38

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:47:59
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'No (N)'	Lauren Evans (b) (4)	22 Dec 2020 19:03:38

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:47:59
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 03:25:08
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' answered with 'no AE needed per investigator' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	01 Feb 2021 17:06:42
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 10:02:20
User entered 'seasonal allergies'	Lauren Evans (b) (4)	22 Dec 2020 19:03:38

FDA-CBER-2022-1614-3182173

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:47:59
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered '10'	Lauren Evans (b) (4)	22 Dec 2020 19:03:38

FDA-CBER-2022-1614-3182174

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:47:59
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'mg (mg)'	Lauren Evans (b) (4)	22 Dec 2020 19:03:38

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:47:59
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered empty.	Lauren Evans (b) (4)	22 Dec 2020 19:03:38

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:47:59
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'once daily (QD)'	Lauren Evans (b) (4)	22 Dec 2020 19:03:38

FDA-CBER-2022-1614-3182177

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:47:59
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered empty.	Lauren Evans (b) (4)	22 Dec 2020 19:03:38

FDA-CBER-2022-1614-3182178

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:47:59
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'Oral (ORAL)'	Lauren Evans (b) (4)	22 Dec 2020 19:03:38

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:47:59
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered empty.	Lauren Evans (b) (4)	22 Dec 2020 19:03:38

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:47:59
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
User entered '07 May 2020'	Lauren Evans (b) (4)	22 Dec 2020 19:03:38

FDA-CBER-2022-1614-3182181

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:47:59
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered '0'	Lauren Evans (b) (4)	22 Dec 2020 19:03:38

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:47:59
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'Yes (Y)'	Lauren Evans (b) (4)	22 Dec 2020 19:03:38

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:47:59
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered empty.	Lauren Evans (b) (4)	22 Dec 2020 19:03:38

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:47:59
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'No (N)'	Lauren Evans (b) (4)	22 Dec 2020 19:03:38

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:47:59
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '1'	System	22 Dec 2020 19:03:38

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:47:59
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '1'	System	22 Dec 2020 19:03:38

FDA-CBER-2022-1614-3182187

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 10 Jun 2021 09:47:59
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '804 (804)'	System	22 Dec 2020 19:03:38

FDA-CBER-2022-1614-3182188

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:47:59
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: ATENOLOL, PRODUCTSYNONYM: STANOL [ATENOLOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Dec 2020 18:09:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Dec 2020 18:09:42
Data point term sent to Coder	System	22 Dec 2020 19:28:48
User entered 'plant stanol ester'	Lauren Evans (b) (4)	22 Dec 2020 19:28:29

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:47:59
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'No (N)'	Lauren Evans (b) (4)	22 Dec 2020 19:28:29

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:47:59
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'heart health'	Lauren Evans (b) (4)	22 Dec 2020 19:28:29

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:47:59
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered '2'	Lauren Evans (b) (4)	22 Dec 2020 19:28:29

FDA-CBER-2022-1614-3182192

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:47:59
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'capsule (CAPSULE)'	Lauren Evans (b) (4)	22 Dec 2020 19:28:29

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:47:59
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered empty.	Lauren Evans (b) (4)	22 Dec 2020 19:28:29

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:47:59
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
User entered 'once daily (QD)'	Lauren Evans (b) (4)	22 Dec 2020 19:28:29

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:47:59
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered empty.	Lauren Evans (b) (4)	22 Dec 2020 19:28:29

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:47:59
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'Oral (ORAL)'	Lauren Evans (b) (4)	22 Dec 2020 19:28:29

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:47:59
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered empty.	Lauren Evans (b) (4)	22 Dec 2020 19:28:29

FDA-CBER-2022-1614-3182198

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:47:59
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered '14 May 2018'	Lauren Evans (b) (4)	22 Dec 2020 19:28:29

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:47:59
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered '0'	Lauren Evans (b) (4)	22 Dec 2020 19:28:29

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:47:59
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'Yes (Y)'	Lauren Evans (b) (4)	22 Dec 2020 19:28:29

FDA-CBER-2022-1614-3182201

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:47:59
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered empty.	Lauren Evans (b) (4)	22 Dec 2020 19:28:29

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:47:59
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'No (N)'	Lauren Evans (b) (4)	22 Dec 2020 19:28:29

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:47:59
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '1'	System	22 Dec 2020 19:28:29

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:47:59
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '1'	System	22 Dec 2020 19:28:29

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 10 Jun 2021 09:47:59
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '804 (804)'	System	22 Dec 2020 19:28:29

FDA-CBER-2022-1614-3182206

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:47:59
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH DIRECT CARDIAC EFFECTS, ATC: BENZOTHIAZEPINE DERIVATIVES, PRODUCT: DILTIAZEM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Dec 2020 21:24:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Dec 2020 21:24:46
Data point term sent to Coder	System	22 Dec 2020 19:30:50
User entered 'diltiazem'	Lauren Evans (b) (4)	22 Dec 2020 19:30:31

FDA-CBER-2022-1614-3182207

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:47:59
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'No (N)'	Lauren Evans (b) (4)	22 Dec 2020 19:30:31

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:47:59
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'atrial flutter'	Lauren Evans (b) (4)	22 Dec 2020 19:30:31

FDA-CBER-2022-1614-3182209

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:47:59
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered '10'	Lauren Evans (b) (4)	22 Dec 2020 19:30:31

FDA-CBER-2022-1614-3182210

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:47:59
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'mg (mg)'	Lauren Evans (b) (4)	22 Dec 2020 19:30:31

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:47:59
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered empty.	Lauren Evans (b) (4)	22 Dec 2020 19:30:31

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:47:59
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'twice daily (BID)'	Lauren Evans (b) (4)	22 Dec 2020 19:30:31

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:47:59
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered empty.	Lauren Evans (b) (4)	22 Dec 2020 19:30:31

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:47:59
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'Intravenous (INTRAVENOUS)'	Lauren Evans (b) (4)	22 Dec 2020 19:30:31

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:47:59
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered empty.	Lauren Evans (b) (4)	22 Dec 2020 19:30:31

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:47:59
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered '20 Dec 2020'	Lauren Evans (b) (4)	22 Dec 2020 19:30:31

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:47:59
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered '0'	Lauren Evans (b) (4)	22 Dec 2020 19:30:31

FDA-CBER-2022-1614-3182218

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:47:59
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'No (N)'	Lauren Evans (b) (4)	22 Dec 2020 19:30:31

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:47:59
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered '21 Dec 2020'	Lauren Evans (b) (4)	22 Dec 2020 19:30:31

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:47:59
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User closed query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 11:07:45
Query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify. ' answered with 'data updated' (Site from DM).	Jamie Pettus (b) (4)	01 Feb 2021 17:07:26
User entered 'No (N)' reason for change: Data Entry Error	Jamie Pettus (b) (4)	01 Feb 2021 17:07:17
User opened query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 10:06:32
User entered 'Yes (Y)'	Lauren Evans (b) (4)	22 Dec 2020 19:30:31

FDA-CBER-2022-1614-3182221

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:47:59
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '2'	System	22 Dec 2020 19:30:31

FDA-CBER-2022-1614-3182222

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:47:59
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '1'	System	22 Dec 2020 19:30:31

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 10 Jun 2021 09:47:59
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '804 (804)'	System	22 Dec 2020 19:30:31

FDA-CBER-2022-1614-3182224

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:47:59
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH DIRECT CARDIAC EFFECTS, ATC: BENZOTHIAZEPINE DERIVATIVES, PRODUCT: DILTIAZEM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Dec 2020 21:27:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Dec 2020 21:27:49
Data point term sent to Coder	System	22 Dec 2020 19:34:55
User entered 'Diltiazem in Normal Saline'	Lauren Evans (b) (4)	22 Dec 2020 19:33:59

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:47:59
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'No (N)'	Lauren Evans (b) (4)	22 Dec 2020 19:33:59

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:47:59
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'atrial flutter'	Lauren Evans (b) (4)	22 Dec 2020 19:33:59

FDA-CBER-2022-1614-3182227

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:47:59
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered '100'	Lauren Evans (b) (4)	22 Dec 2020 19:33:59

FDA-CBER-2022-1614-3182228

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:47:59
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'mg (mg)'	Lauren Evans (b) (4)	22 Dec 2020 19:33:59

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:47:59
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered empty.	Lauren Evans (b) (4)	22 Dec 2020 19:33:59

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:47:59
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	22 Dec 2020 19:34:38
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	22 Dec 2020 19:34:38
User entered 'once daily (QD)' reason for change: Data Entry Error	Lauren Evans (b) (4)	22 Dec 2020 19:34:38
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	22 Dec 2020 19:33:59
User entered 'once (ONCE)'	Lauren Evans (b) (4)	22 Dec 2020 19:33:59

FDA-CBER-2022-1614-3182231

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:47:59
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered empty.	Lauren Evans (b) (4)	22 Dec 2020 19:33:59

FDA-CBER-2022-1614-3182232

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:47:59
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'Intravenous (INTRAVENOUS)'	Lauren Evans (b) (4)	22 Dec 2020 19:33:59

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:47:59
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered empty.	Lauren Evans (b) (4)	22 Dec 2020 19:33:59

FDA-CBER-2022-1614-3182234

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:47:59
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered '20 Dec 2020'	Lauren Evans (b) (4)	22 Dec 2020 19:33:59

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:47:59
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered '0'	Lauren Evans (b) (4)	22 Dec 2020 19:33:59

FDA-CBER-2022-1614-3182236

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:47:59
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'No (N)'	Lauren Evans (b) (4)	22 Dec 2020 19:33:59

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:47:59
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered '21 Dec 2020'	Lauren Evans (b) (4)	22 Dec 2020 19:33:59

FDA-CBER-2022-1614-3182238

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:47:59
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User closed query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 11:07:53
Query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify. ' answered with 'data updated' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	01 Feb 2021 17:08:35
User entered 'No (N)' reason for change: Data Entry Error	Jamie Pettus (b) (4) (b) (4)	01 Feb 2021 17:08:20
User opened query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 10:06:40
User entered 'Yes (Y)'	Lauren Evans (b) (4)	22 Dec 2020 19:33:59

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:47:59
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '1'	System	22 Dec 2020 19:34:38
User entered empty.	System	22 Dec 2020 19:33:59

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:47:59
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '1'	System	22 Dec 2020 19:34:38
User entered empty.	System	22 Dec 2020 19:33:59

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 10 Jun 2021 09:47:59
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '804 (804)'	System	22 Dec 2020 19:34:38
User entered empty.	System	22 Dec 2020 19:33:59

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:47:59
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Dec 2020 21:28:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Dec 2020 21:28:52
Data point term sent to Coder	System	22 Dec 2020 19:36:57
User entered 'enoxaparin'	Lauren Evans (b) (4)	22 Dec 2020 19:36:45

FDA-CBER-2022-1614-3182243

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:47:59
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User closed query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 03:23:23
Query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify.' answered with 'data updated' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	01 Feb 2021 17:09:59
User entered 'Yes (Y)' reason for change: Data Entry Error	Jamie Pettus (b) (4) (b) (4)	01 Feb 2021 17:09:42
User opened query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 10:07:07
User entered 'No (N)'	Lauren Evans (b) (4)	22 Dec 2020 19:36:45

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:47:59
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'blood clot prevention'	Lauren Evans (b) (4)	22 Dec 2020 19:36:45

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US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:47:59
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered '90'	Lauren Evans (b) (4)	22 Dec 2020 19:36:45

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US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:47:59
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'mg (mg)'	Lauren Evans (b) (4)	22 Dec 2020 19:36:45

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:47:59
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered empty.	Lauren Evans (b) (4)	22 Dec 2020 19:36:45

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:47:59
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'once daily (QD)'	Lauren Evans (b) (4)	22 Dec 2020 19:36:45

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:47:59
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered empty.	Lauren Evans (b) (4)	22 Dec 2020 19:36:45

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:47:59
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'Subcutaneous (SUBCUTANEOUS)'	Lauren Evans (b) (4)	22 Dec 2020 19:36:45

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:47:59
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered empty.	Lauren Evans (b) (4)	22 Dec 2020 19:36:45

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:47:59
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered '20 Dec 2020'	Lauren Evans (b) (4)	22 Dec 2020 19:36:45

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:47:59
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered '0'	Lauren Evans (b) (4)	22 Dec 2020 19:36:45

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US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:47:59
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'No (N)'	Lauren Evans (b) (4)	22 Dec 2020 19:36:45

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:47:59
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered '21 Dec 2020'	Lauren Evans (b) (4)	22 Dec 2020 19:36:45

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:47:59
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User closed query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 03:23:31
Query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify' answered with 'data updated' (Site from DM).	Jamie Pettus (b) (4)	01 Feb 2021 17:10:09
User entered 'No (N)' reason for change: Data Entry Error	Jamie Pettus (b) (4)	01 Feb 2021 17:09:42
User opened query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 10:07:26
User entered 'Yes (Y)'	Lauren Evans (b) (4)	22 Dec 2020 19:36:45

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US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:47:59
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '1'	System	22 Dec 2020 19:36:45

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US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:47:59
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '1'	System	22 Dec 2020 19:36:45

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 10 Jun 2021 09:47:59
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '804 (804)'	System	22 Dec 2020 19:36:45

FDA-CBER-2022-1614-3182260

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 10 Jun 2021 09:47:59
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Dec 2020 22:16:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Dec 2020 22:16:46
Data point term sent to Coder	System	22 Dec 2020 19:39:01
User entered 'Heparin'	Lauren Evans (b) (4)	22 Dec 2020 19:38:53

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US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 10 Jun 2021 09:47:59
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User closed query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 03:21:56
Query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify.' answered with 'data updated' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	01 Feb 2021 17:11:05
User entered 'Yes (Y)' reason for change: Data Entry Error	Jamie Pettus (b) (4) (b) (4)	01 Feb 2021 17:10:49
User opened query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 10:08:25
User entered 'No (N)'	Lauren Evans (b) (4)	22 Dec 2020 19:38:53

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 10 Jun 2021 09:47:59
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'blood clot prevention'	Lauren Evans (b) (4)	22 Dec 2020 19:38:53

FDA-CBER-2022-1614-3182263

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 10 Jun 2021 09:47:59
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered '25000'	Lauren Evans (b) (4)	22 Dec 2020 19:38:53

FDA-CBER-2022-1614-3182264

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 10 Jun 2021 09:47:59
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'IU (IU)'	Lauren Evans (b) (4)	22 Dec 2020 19:38:53

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 10 Jun 2021 09:47:59
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered empty.	Lauren Evans (b) (4)	22 Dec 2020 19:38:53

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 10 Jun 2021 09:47:59
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'once daily (QD)'	Lauren Evans (b) (4)	22 Dec 2020 19:38:53

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 10 Jun 2021 09:47:59
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered empty.	Lauren Evans (b) (4)	22 Dec 2020 19:38:53

FDA-CBER-2022-1614-3182268

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 10 Jun 2021 09:47:59
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'Intravenous (INTRAVENOUS)'	Lauren Evans (b) (4)	22 Dec 2020 19:38:53

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 10 Jun 2021 09:47:59
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered empty.	Lauren Evans (b) (4)	22 Dec 2020 19:38:53

FDA-CBER-2022-1614-3182270

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 10 Jun 2021 09:47:59
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered '20 Dec 2020'	Lauren Evans (b) (4)	22 Dec 2020 19:38:53

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 10 Jun 2021 09:47:59
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered '0'	Lauren Evans (b) (4)	22 Dec 2020 19:38:53

FDA-CBER-2022-1614-3182272

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 10 Jun 2021 09:47:59
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'No (N)'	Lauren Evans (b) (4)	22 Dec 2020 19:38:53

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 10 Jun 2021 09:47:59
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered '21 Dec 2020'	Lauren Evans (b) (4)	22 Dec 2020 19:38:53

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 10 Jun 2021 09:47:59
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User closed query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 03:22:39
Query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' answered with 'data updated' (Site from DM).	Jamie Pettus (b) (4)	01 Feb 2021 17:11:12
User entered 'No (N)' reason for change: Data Entry Error	Jamie Pettus (b) (4)	01 Feb 2021 17:10:49
User opened query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 10:08:36
User entered 'Yes (Y)'	Lauren Evans (b) (4)	22 Dec 2020 19:38:53

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 10 Jun 2021 09:47:59
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '1'	System	22 Dec 2020 19:38:53

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 10 Jun 2021 09:47:59
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '1'	System	22 Dec 2020 19:38:53

FDA-CBER-2022-1614-3182277

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 10 Jun 2021 09:47:59
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '804 (804)'	System	22 Dec 2020 19:38:53

FDA-CBER-2022-1614-3182278

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 10 Jun 2021 09:47:59
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening ESSENTIAL HYPERTENSION should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 03:23:44
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening ESSENTIAL HYPERTENSION should be recorded, and update con med indication or provide clarification. ' answered with 'No AE needed per investigator' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	01 Feb 2021 17:11:40
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening ESSENTIAL HYPERTENSION should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 01:50:24
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL SUCCINATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Dec 2020 23:55:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Dec 2020 23:55:52
Data point term sent to Coder	System	22 Dec 2020 19:40:02
User entered 'Metoprolol succinate'	Lauren Evans (b) (4)	22 Dec 2020 19:39:51

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 10 Jun 2021 09:47:59
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'No (N)'	Lauren Evans (b) (4)	22 Dec 2020 19:39:51

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 10 Jun 2021 09:47:59
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'essential hypertension'	Lauren Evans (b) (4)	22 Dec 2020 19:39:51

FDA-CBER-2022-1614-3182281

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 10 Jun 2021 09:47:59
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered '50'	Lauren Evans (b) (4)	22 Dec 2020 19:39:51

FDA-CBER-2022-1614-3182282

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 10 Jun 2021 09:47:59
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'mg (mg)'	Lauren Evans (b) (4)	22 Dec 2020 19:39:51

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 10 Jun 2021 09:47:59
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered empty.	Lauren Evans (b) (4)	22 Dec 2020 19:39:51

FDA-CBER-2022-1614-3182284

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 10 Jun 2021 09:47:59
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'once daily (QD)'	Lauren Evans (b) (4)	22 Dec 2020 19:39:51

FDA-CBER-2022-1614-3182285

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 10 Jun 2021 09:47:59
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered empty.	Lauren Evans (b) (4)	22 Dec 2020 19:39:51

FDA-CBER-2022-1614-3182286

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 10 Jun 2021 09:47:59
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'Oral (ORAL)'	Lauren Evans (b) (4)	22 Dec 2020 19:39:51

FDA-CBER-2022-1614-3182287

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 10 Jun 2021 09:47:59
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered empty.	Lauren Evans (b) (4)	22 Dec 2020 19:39:51

FDA-CBER-2022-1614-3182288

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 10 Jun 2021 09:47:59
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered '22 Dec 2020'	Lauren Evans (b) (4)	22 Dec 2020 19:39:51

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 10 Jun 2021 09:47:59
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered '0'	Lauren Evans (b) (4)	22 Dec 2020 19:39:51

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 10 Jun 2021 09:47:59
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'Yes (Y)'	Lauren Evans (b) (4)	22 Dec 2020 19:39:51

FDA-CBER-2022-1614-3182291

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 10 Jun 2021 09:47:59
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered empty.	Lauren Evans (b) (4)	22 Dec 2020 19:39:51

FDA-CBER-2022-1614-3182292

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 10 Jun 2021 09:47:59
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'Yes (Y)'	Lauren Evans (b) (4)	22 Dec 2020 19:39:51

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 10 Jun 2021 09:47:59
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '1'	System	22 Dec 2020 19:39:51

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 10 Jun 2021 09:47:59
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '1'	System	22 Dec 2020 19:39:51

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 10 Jun 2021 09:47:59
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '804 (804)'	System	22 Dec 2020 19:39:51

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 10 Jun 2021 09:47:59
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:52:14
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Jan 2021 15:13:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Jan 2021 15:13:53
Data point term sent to Coder	System	25 Jan 2021 15:13:05
User entered 'Eliquis'	Jamie Pettus (b) (4) (b) (4)	25 Jan 2021 15:12:05

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 10 Jun 2021 09:47:59
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	19 Mar 2021 14:58:14
User closed query 'please verify as yes-maintenance for a-flutter' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 14:58:08
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Mar 2021 16:22:02
Query 'please verify as yes-maintenance for a-flutter' answered with 'updated' (Site from CRA).	Jamie Pettus (b) (4) (b) (4)	10 Mar 2021 19:11:23
Signature has been broken.	Jamie Pettus (b) (4) (b) (4)	10 Mar 2021 19:11:05
User entered 'Yes (Y)' reason for change: Data Entry Error	Jamie Pettus (b) (4) (b) (4)	10 Mar 2021 19:11:05
DataPoint Un-verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:43
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User opened query 'please verify as yes-maintenance for a-flutter' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 21:01:14
DataPoint Un-verified.	(b) (4), (b) (6)	08 Mar 2021 20:52:21
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:52:19
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'No (N)'	Jamie Pettus (b) (4) (b) (4)	25 Jan 2021 15:12:05

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 10 Jun 2021 09:47:59
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:52:23
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'atrial flutter'	Jamie Pettus (b) (4) (b) (4)	25 Jan 2021 15:12:05

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 10 Jun 2021 09:47:59
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:52:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered '5'	Jamie Pettus (b) (4) (b) (4)	25 Jan 2021 15:12:05

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 10 Jun 2021 09:47:59
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:52:31
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'mg (mg)'	Jamie Pettus (b) (4) (b) (4)	25 Jan 2021 15:12:05

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 10 Jun 2021 09:47:59
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:52:33
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered empty.	Jamie Pettus (b) (4) (b) (4)	25 Jan 2021 15:12:05

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 10 Jun 2021 09:47:59
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:52:36
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'twice daily (BID)'	Jamie Pettus (b) (4) (b) (4)	25 Jan 2021 15:12:05

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 10 Jun 2021 09:47:59
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:52:39
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered empty.	Jamie Pettus (b) (4) (b) (4)	25 Jan 2021 15:12:05

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 10 Jun 2021 09:47:59
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:52:38
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'Oral (ORAL)'	Jamie Pettus (b) (4) (b) (4)	25 Jan 2021 15:12:05

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 10 Jun 2021 09:47:59
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:52:42
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered empty.	Jamie Pettus (b) (4) (b) (4)	25 Jan 2021 15:12:05

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 10 Jun 2021 09:47:59
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered '20 Jan 2021'	Jamie Pettus (b) (4) (b) (4)	25 Jan 2021 15:12:05

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 10 Jun 2021 09:47:59
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered '0'	Jamie Pettus (b) (4) (b) (4)	25 Jan 2021 15:12:05

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 10 Jun 2021 09:47:59
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 12:54:19
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' answered with 'updated' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	10 Mar 2021 19:12:12
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	21 Feb 2021 13:18:19
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'Yes (Y)'	Jamie Pettus (b) (4) (b) (4)	25 Jan 2021 15:12:05

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 10 Jun 2021 09:47:59
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:53:11
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered empty.	Jamie Pettus (b) (4) (b) (4)	25 Jan 2021 15:12:05

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 10 Jun 2021 09:47:59
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:53:07
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'No (N)'	Jamie Pettus (b) (4) (b) (4)	25 Jan 2021 15:12:05

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 10 Jun 2021 09:47:59
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '2'	System	25 Jan 2021 15:12:05

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 10 Jun 2021 09:47:59
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '1'	System	25 Jan 2021 15:12:05

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US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 10 Jun 2021 09:47:59
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '804 (804)'	System	25 Jan 2021 15:12:05

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 10 Jun 2021 09:47:59
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User closed query 'Per MM, please confirm if this meets EC #4 'Prior administration of an investigational coronavirus (SARS-CoV, MERS-CoV) vaccine or current/planned simultaneous participation in another interventional study to prevent or treat COVID-19', if so please raise a PD accordingly. ' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 14:22:34
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: OTHER VIRAL VACCINES, PRODUCT: OTHER VIRAL VACCINES - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Mar 2021 19:14:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Mar 2021 19:14:55
Data point term sent to Coder	System	10 Mar 2021 19:13:59
Query 'Per MM, please confirm if this meets EC #4 'Prior administration of an investigational coronavirus (SARS-CoV, MERS-CoV) vaccine or current/planned simultaneous participation in another interventional study to prevent or treat COVID-19', if so please raise a PD accordingly. ' answered with 'early termination' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	10 Mar 2021 19:13:40
Coding entries removed.	Jamie Pettus (b) (4) (b) (4)	10 Mar 2021 19:13:06
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:01:31
User opened query 'Per MM, please confirm if this meets EC #4 'Prior administration of an investigational coronavirus (SARS-CoV, MERS-CoV) vaccine or current/planned simultaneous participation in another interventional study to prevent or treat COVID-19', if so please raise a PD accordingly. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 21:21:51
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12

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US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 10 Jun 2021 09:47:59
Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: OTHER VIRAL VACCINES, PRODUCT: OTHER VIRAL VACCINES - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Jan 2021 23:44:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Jan 2021 23:44:59
Data point term sent to Coder	System	25 Jan 2021 15:36:32
User entered 'pfizer covid vaccine'	Jamie Pettus (b) (4) (b) (4)	25 Jan 2021 15:35:36

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US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 10 Jun 2021 09:47:59
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:01:35
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'Yes (Y)'	Jamie Pettus (b) (4) (b) (4)	25 Jan 2021 15:35:36

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 10 Jun 2021 09:47:59
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:15:13
User closed query 'please correct spelling' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 14:58:23
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Mar 2021 16:22:02
Query 'please correct spelling' answered with 'done' (Site from CRA).	Jamie Pettus (b) (4) (b) (4)	10 Mar 2021 19:13:45
Signature has been broken.	Jamie Pettus (b) (4) (b) (4)	10 Mar 2021 19:13:06
User entered 'COVID PREVENTION' reason for change: Data Entry Error	Jamie Pettus (b) (4) (b) (4)	10 Mar 2021 19:13:06
DataPoint Un-verified.	(b) (4), (b) (6)	08 Mar 2021 21:07:16
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:06:29
User opened query 'please correct spelling' (Site from CRA).	(b) (4), (b) (6)	08 Mar 2021 21:04:39
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'coivd prevention'	Jamie Pettus (b) (4) (b) (4)	25 Jan 2021 15:35:36

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 10 Jun 2021 09:47:59
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:04:43
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered '0.3'	Jamie Pettus (b) (4) (b) (4)	25 Jan 2021 15:35:36

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 10 Jun 2021 09:47:59
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:04:44
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'mL (mL)'	Jamie Pettus (b) (4) (b) (4)	25 Jan 2021 15:35:36

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 10 Jun 2021 09:47:59
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:04:47
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered empty.	Jamie Pettus (b) (4) (b) (4)	25 Jan 2021 15:35:36

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 10 Jun 2021 09:47:59
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:04:49
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'once (ONCE)'	Jamie Pettus (b) (4) (b) (4)	25 Jan 2021 15:35:36

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 10 Jun 2021 09:47:59
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:04:50
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered empty.	Jamie Pettus (b) (4) (b) (4)	25 Jan 2021 15:35:36

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 10 Jun 2021 09:47:59
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:04:52
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Jamie Pettus (b) (4) (b) (4)	25 Jan 2021 15:35:36

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US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 10 Jun 2021 09:47:59
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:04:55
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered empty.	Jamie Pettus (b) (4) (b) (4)	25 Jan 2021 15:35:36

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 10 Jun 2021 09:47:59
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:04:56
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered '12 Jan 2021'	Jamie Pettus (b) (4) (b) (4)	25 Jan 2021 15:35:36

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 10 Jun 2021 09:47:59
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:04:58
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered '0'	Jamie Pettus (b) (4) (b) (4)	25 Jan 2021 15:35:36

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 10 Jun 2021 09:47:59
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:05:01
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'No (N)'	Jamie Pettus (b) (4) (b) (4)	25 Jan 2021 15:35:36

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 10 Jun 2021 09:47:59
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:01:41
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered '12 Jan 2021'	Jamie Pettus (b) (4) (b) (4)	25 Jan 2021 15:35:36

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US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 10 Jun 2021 09:47:59
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:05:03
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'No (N)'	Jamie Pettus (b) (4) (b) (4)	25 Jan 2021 15:35:36

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 10 Jun 2021 09:47:59
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	25 Jan 2021 15:35:36

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 10 Jun 2021 09:47:59
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	25 Jan 2021 15:35:36

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 10 Jun 2021 09:47:59
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	25 Jan 2021 15:35:36

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 10 Jun 2021 09:47:59
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User closed query 'Per MM, please confirm if this meets EC #4 'Prior administration of an investigational coronavirus (SARS-CoV, MERS-CoV) vaccine or current/planned simultaneous participation in another interventional study to prevent or treat COVID-19', if so please raise a PD accordingly. ' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 15:21:05
Query 'Per MM, please confirm if this meets EC #4 'Prior administration of an investigational coronavirus (SARS-CoV, MERS-CoV) vaccine or current/planned simultaneous participation in another interventional study to prevent or treat COVID-19', if so please raise a PD accordingly. ' answered with 'This subject did not get the Pfizer vaccine until after signing consent and after the Emergency Use Authorization was approved which we were given guidelines from Moderna on what to do (document and drop subject due to receiving EUA vaccine outside of study and note deviation)' (Site from DM).	Haylee Rowe (b) (4) (b) (4)	30 Mar 2021 13:58:05
User opened query 'Per MM, please confirm if this meets EC #4 'Prior administration of an investigational coronavirus (SARS-CoV, MERS-CoV) vaccine or current/planned simultaneous participation in another interventional study to prevent or treat COVID-19', if so please raise a PD accordingly. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 00:51:30
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:03:17
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: OTHER VIRAL VACCINES, PRODUCT: OTHER VIRAL VACCINES - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Feb 2021 21:01:49

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 10 Jun 2021 09:47:59
Name of Medication

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Feb 2021 21:01:49
Data point term sent to Coder	System	03 Feb 2021 16:04:58
User entered 'PFIZER COVID VACCINE'	Haylee Rowe (b) (4) (b) (4)	03 Feb 2021 16:04:57

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 10 Jun 2021 09:47:59
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:03:19
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'Yes (Y)'	Haylee Rowe (b) (4) (b) (4)	03 Feb 2021 16:04:57

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 10 Jun 2021 09:47:59
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:03:21
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'COVID PREVENTATIVE'	Haylee Rowe (b) (4) (b) (4)	03 Feb 2021 16:04:57

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 10 Jun 2021 09:47:59
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:03:24
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered '0.3'	Haylee Rowe (b) (4) (b) (4)	03 Feb 2021 16:04:57

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US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 10 Jun 2021 09:47:59
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:03:25
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'mL (mL)'	Haylee Rowe (b) (4) (b) (4)	03 Feb 2021 16:04:57

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 10 Jun 2021 09:47:59
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:03:28
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered empty.	Haylee Rowe (b) (4) (b) (4)	03 Feb 2021 16:04:57

FDA-CBER-2022-1614-3182340

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 10 Jun 2021 09:47:59
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:03:30
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'once (ONCE)'	Haylee Rowe (b) (4) (b) (4)	03 Feb 2021 16:04:57

FDA-CBER-2022-1614-3182341

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 10 Jun 2021 09:47:59
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:03:32
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered empty.	Haylee Rowe (b) (4) (b) (4)	03 Feb 2021 16:04:57

FDA-CBER-2022-1614-3182342

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 10 Jun 2021 09:47:59
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:03:34
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'Intramuscular (INTRAMUSCULAR)'	Haylee Rowe (b) (4) (b) (4)	03 Feb 2021 16:04:57

FDA-CBER-2022-1614-3182343

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 10 Jun 2021 09:47:59
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:03:36
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered empty.	Haylee Rowe (b) (4) (b) (4)	03 Feb 2021 16:04:57

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 10 Jun 2021 09:47:59
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:03:39
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered '02 Feb 2021'	Haylee Rowe (b) (4) (b) (4)	03 Feb 2021 16:04:57

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 10 Jun 2021 09:47:59
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:03:40
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered '0'	Haylee Rowe (b) (4) (b) (4)	03 Feb 2021 16:04:57

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 10 Jun 2021 09:47:59
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:03:42
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'No (N)'	Haylee Rowe (b) (4) (b) (4)	03 Feb 2021 16:04:57

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 10 Jun 2021 09:47:59
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:03:49
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered '02 Feb 2021'	Haylee Rowe (b) (4) (b) (4)	03 Feb 2021 16:04:57

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 10 Jun 2021 09:47:59
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:03:51
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'No (N)'	Haylee Rowe (b) (4) (b) (4)	03 Feb 2021 16:04:57

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 10 Jun 2021 09:47:59
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	03 Feb 2021 16:04:57

US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 10 Jun 2021 09:47:59
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	03 Feb 2021 16:04:57

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US3752259
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 10 Jun 2021 09:47:59
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered empty.	System	03 Feb 2021 16:04:57

FDA-CBER-2022-1614-3182352

US3752259
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Generated On: 10 Jun 2021 09:47:59
Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:59:45
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'Yes (Y)'	Lauren Evans (b) (4)	22 Dec 2020 18:50:51

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US3752259
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (1)
Generated On: 10 Jun 2021 09:47:59
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:00:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered '20 Dec 2020'	Lauren Evans (b) (4)	22 Dec 2020 18:52:39

US3752259
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (1)
Generated On: 10 Jun 2021 09:47:59
Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:00:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'Echo TTE'	Lauren Evans (b) (4)	22 Dec 2020 18:52:39

US3752259
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (1)
Generated On: 10 Jun 2021 09:47:59
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:00:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'Adverse Event (AE)'	Lauren Evans (b) (4)	22 Dec 2020 18:52:39

US3752259
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (1)
Generated On: 10 Jun 2021 09:47:59
If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:00:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered empty.	Lauren Evans (b) (4)	22 Dec 2020 18:52:39

US3752259
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (2)
Generated On: 10 Jun 2021 09:47:59
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:00:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered '21 Dec 2020'	Lauren Evans (b) (4)	22 Dec 2020 18:53:22

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US3752259
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (2)
Generated On: 10 Jun 2021 09:47:59
Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:00:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'EP-Cardioversion with transesophageal echo'	Lauren Evans (b) (4)	22 Dec 2020 18:53:22

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US3752259
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (2)
Generated On: 10 Jun 2021 09:47:59
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:00:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'Adverse Event (AE)'	Lauren Evans (b) (4)	22 Dec 2020 18:53:22

US3752259
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (2)
Generated On: 10 Jun 2021 09:47:59
If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 21:00:12
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered empty.	Lauren Evans (b) (4)	22 Dec 2020 18:53:22

US3752259
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 10 Jun 2021 09:47:59
Date of study discontinuation/completion *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:53:59
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered '03 Feb 2021'	Haylee Rowe (b) (4) (b) (4)	03 Feb 2021 16:05:56

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US3752259
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 10 Jun 2021 09:47:59
Reason for discontinuation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	10 Apr 2021 19:14:35
User signature succeeded.	Priyantha Wijewardane (b) (4)	08 Apr 2021 13:41:31
User closed query 'Per CDM: Per Sponsor review, subject took a vaccine outside of the study. Please agree to update the Reason for discontinuation to Protocol Deviation. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 11:54:41
Query 'Per CDM: Per Sponsor review, subject took a vaccine outside of the study. Please agree to update the Reason for discontinuation to Protocol Deviation. ' answered with 'data updated per query' (Site from DM).	Lauren Evans (b) (4)	06 Apr 2021 18:23:28
DataPoint Un-verified.	Lauren Evans (b) (4)	06 Apr 2021 18:23:02
Signature has been broken.	Lauren Evans (b) (4)	06 Apr 2021 18:23:02
User entered 'Protocol deviation (specify) (PROTOCOL DEVIATION)' reason for change: Data Entry Error	Lauren Evans (b) (4)	06 Apr 2021 18:23:02
User closed query 'Per CDM: Per Sponsor Review, if subject received EUA vaccine outside of study, discontinuation reason is to be recorded as Protocol Deviation. Please review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 18:06:09
User opened query 'Per CDM: Per Sponsor review, subject took a vaccine outside of the study. Please agree to update the Reason for discontinuation to Protocol Deviation. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 17:58:17
Query 'Per CDM: Per Sponsor Review, if subject received EUA vaccine outside of study, discontinuation reason is to be recorded as Protocol Deviation. Please review and update as appropriate.' answered with 'deviation filed' (Site from DM).	Jamie Pettus (b) (4) (b) (4)	22 Mar 2021 15:56:39

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US3752259
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 10 Jun 2021 09:47:59
Reason for discontinuation

Audit	User	Time (GMT)
User opened query 'Per CDM: Per Sponsor Review, if subject received EUA vaccine outside of study, discontinuation reason is to be recorded as Protocol Deviation. Please review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 15:07:40
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:53:59
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered 'Other (OTHER)'	Haylee Rowe (b) (4) (b) (4)	03 Feb 2021 16:05:56

US3752259
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 10 Jun 2021 09:47:59
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 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:53:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
User entered 'PATIENT RECEIVED THE PFIZER COVID VACCINE OUTSIDE OF THE STUDY SO IS THEREFORE BEING WITHDRAWN'	Haylee Rowe (b) (4) (b) (4)	03 Feb 2021 16:05:56

US3752259
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 10 Jun 2021 09:47:59
If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:53:59
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered empty.	Haylee Rowe (b) (4) (b) (4)	03 Feb 2021 16:05:56

US3752259
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 10 Jun 2021 09:47:59
If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:53:59
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered empty.	Haylee Rowe (b) (4) (b) (4)	03 Feb 2021 16:05:56

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US3752259
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 10 Jun 2021 09:47:59
Date of death *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:53:59
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered empty.	Haylee Rowe (b) (4) (b) (4)	03 Feb 2021 16:05:56

FDA-CBER-2022-1614-3182368

US3752259
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 10 Jun 2021 09:47:59
Was autopsy performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:53:59
User signature succeeded.	Priyantha Wijewardane (b) (4)	12 Feb 2021 19:15:12
User entered empty.	Haylee Rowe (b) (4) (b) (4)	03 Feb 2021 16:05:56

FDA-CBER-2022-1614-3182369

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:56:57
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'USA-US113-2020-MRNA-1273-P301000015'	System	22 Dec 2020 20:51:57

FDA-CBER-2022-1614-3182370

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:56:55
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'Yes (Y)'	System	22 Dec 2020 20:51:57

FDA-CBER-2022-1614-3182371

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:56:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'No (N)'	System	22 Dec 2020 20:51:57

FDA-CBER-2022-1614-3182372

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:56:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'No (N)'	System	22 Dec 2020 20:51:57

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:57:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'Yes (Y)'	System	22 Dec 2020 20:51:57

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US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:57:03
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'No (N)'	System	22 Dec 2020 20:51:57

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:57:06
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'No (N)'	System	22 Dec 2020 20:51:57

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:57:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'No (N)'	System	22 Dec 2020 20:51:57

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:57:09
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'Priyantha'	System	22 Dec 2020 20:51:57

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:57:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'Wijewardane'	System	22 Dec 2020 20:51:57

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:11:21
User signature succeeded.	Priyantha Wijewardane (b) (4)	13 Apr 2021 01:07:27
User entered '9601 Baptist Health Drive, Medical Tower1, Ste 800'	Lauren Evans (b) (4)	12 Apr 2021 13:50:03

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:11:24
User signature succeeded.	Priyantha Wijewardane (b) (4)	13 Apr 2021 01:07:27
User entered 'Little Rock'	Lauren Evans (b) (4)	12 Apr 2021 13:50:03

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:11:27
User signature succeeded.	Priyantha Wijewardane (b) (4)	13 Apr 2021 01:07:27
User entered 'Arkansas'	Lauren Evans (b) (4)	12 Apr 2021 13:50:03

FDA-CBER-2022-1614-3182382

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:11:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	13 Apr 2021 01:07:27
User entered '72205'	Lauren Evans (b) (4)	12 Apr 2021 13:50:03

FDA-CBER-2022-1614-3182383

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:57:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:59:19
User entered 'US'	System	22 Dec 2020 20:53:35

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '8'	System	07 Apr 2021 15:43:57
User entered '7'	System	29 Mar 2021 16:46:59
User entered '6'	System	17 Mar 2021 15:51:25
User entered '5'	System	10 Mar 2021 16:23:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
	(b) (4)	
User entered '4'	System	06 Jan 2021 15:05:54
User entered '3'	System	30 Dec 2020 14:39:02
User entered '2'	System	29 Dec 2020 14:59:38
User entered '1'	System	22 Dec 2020 20:53:35

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:56:57
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'USA-US113-2020-MRNA-1273-P301000015'	System	22 Dec 2020 20:51:57

FDA-CBER-2022-1614-3182386

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:56:55
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'Yes (Y)'	System	22 Dec 2020 20:51:57

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:56:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'No (N)'	System	22 Dec 2020 20:51:57

FDA-CBER-2022-1614-3182388

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:56:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'No (N)'	System	22 Dec 2020 20:51:57

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:57:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'Yes (Y)'	System	22 Dec 2020 20:51:57

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:57:03
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'No (N)'	System	22 Dec 2020 20:51:57

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:57:06
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'No (N)'	System	22 Dec 2020 20:51:57

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:57:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'No (N)'	System	22 Dec 2020 20:51:57

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:57:09
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'Priyantha'	System	22 Dec 2020 20:51:57

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:57:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'Wijewardane'	System	22 Dec 2020 20:51:57

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:11:21
User signature succeeded.	Priyantha Wijewardane (b) (4)	13 Apr 2021 01:07:27
User entered '9601 Baptist Health Drive, Medical Tower1, Ste 800'	Lauren Evans (b) (4)	12 Apr 2021 13:50:03

FDA-CBER-2022-1614-3182396

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:11:24
User signature succeeded.	Priyantha Wijewardane (b) (4)	13 Apr 2021 01:07:27
User entered 'Little Rock'	Lauren Evans (b) (4)	12 Apr 2021 13:50:03

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:11:27
User signature succeeded.	Priyantha Wijewardane	13 Apr 2021 01:07:27
User entered 'Arkansas'	Lauren Evans (b) (4)	12 Apr 2021 13:50:03

FDA-CBER-2022-1614-3182398

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:11:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	13 Apr 2021 01:07:27
User entered '72205'	Lauren Evans (b) (4)	12 Apr 2021 13:50:03

FDA-CBER-2022-1614-3182399

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:57:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:59:19
User entered 'US'	System	22 Dec 2020 20:53:35

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '8'	System	07 Apr 2021 15:43:57
User entered '7'	System	29 Mar 2021 16:46:59
User entered '6'	System	17 Mar 2021 15:51:25
User entered '5'	System	10 Mar 2021 16:23:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
	(b) (4)	
User entered '4'	System	06 Jan 2021 15:05:54
User entered '3'	System	30 Dec 2020 14:39:02
User entered '2'	System	29 Dec 2020 14:59:38
User entered '1'	System	22 Dec 2020 20:53:35

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form (1)
Generated On: 10 Jun 2021 09:47:59
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:17:02
User closed query 'Please confirm date ' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 15:16:59
Query 'Please confirm date ' answered with 'this date appears to be correct' (Site from CRA).	Lauren Evans (b) (4)	12 Apr 2021 13:52:18
User opened query 'Please confirm date ' (Site from CRA).	(b) (4), (b) (6)	10 Apr 2021 19:27:55
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
User entered '22/Dec/2020 14:53'	(b) (4) System	22 Dec 2020 20:53:35

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form (1)
Generated On: 10 Jun 2021 09:47:59
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 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:17:04
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:59:19
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Dec 2020 20:53:35
User entered '0'	(b) (4), (b) (6)	22 Dec 2020 20:53:26

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:56:57
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'USA-US113-2020-MRNA-1273-P301000015'	System	22 Dec 2020 20:51:57

FDA-CBER-2022-1614-3182404

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:56:55
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'Yes (Y)'	System	22 Dec 2020 20:51:57

FDA-CBER-2022-1614-3182405

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:56:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'No (N)'	System	22 Dec 2020 20:51:57

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:56:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'No (N)'	System	22 Dec 2020 20:51:57

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:57:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'Yes (Y)'	System	22 Dec 2020 20:51:57

FDA-CBER-2022-1614-3182408

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:57:03
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'No (N)'	System	22 Dec 2020 20:51:57

FDA-CBER-2022-1614-3182409

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:57:06
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'No (N)'	System	22 Dec 2020 20:51:57

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:57:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'No (N)'	System	22 Dec 2020 20:51:57

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:57:09
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'Priyantha'	System	22 Dec 2020 20:51:57

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:57:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'Wijewardane'	System	22 Dec 2020 20:51:57

FDA-CBER-2022-1614-3182413

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:11:21
User signature succeeded.	Priyantha Wijewardane (b) (4)	13 Apr 2021 01:07:27
User entered '9601 Baptist Health Drive, Medical Tower1, Ste 800'	Lauren Evans (b) (4)	12 Apr 2021 13:50:03

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:11:24
User signature succeeded.	Priyantha Wijewardane	13 Apr 2021 01:07:27
User entered 'Little Rock'	Lauren Evans (b) (4)	12 Apr 2021 13:50:03

FDA-CBER-2022-1614-3182415

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:11:27
User signature succeeded.	Priyantha Wijewardane (b) (4)	13 Apr 2021 01:07:27
User entered 'Arkansas'	Lauren Evans (b) (4)	12 Apr 2021 13:50:03

FDA-CBER-2022-1614-3182416

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:11:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	13 Apr 2021 01:07:27
User entered '72205'	Lauren Evans (b) (4)	12 Apr 2021 13:50:03

FDA-CBER-2022-1614-3182417

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:57:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:59:19
User entered 'US'	System	22 Dec 2020 20:53:35

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '8'	System	07 Apr 2021 15:43:57
User entered '7'	System	29 Mar 2021 16:46:59
User entered '6'	System	17 Mar 2021 15:51:25
User entered '5'	System	10 Mar 2021 16:23:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
	(b) (4)	
User entered '4'	System	06 Jan 2021 15:05:54
User entered '3'	System	30 Dec 2020 14:39:02
User entered '2'	System	29 Dec 2020 14:59:38
User entered '1'	System	22 Dec 2020 20:53:35

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form (2)
Generated On: 10 Jun 2021 09:47:59
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:56:19
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
User entered '29/Dec/2020 09:59'	(b) (4) System	29 Dec 2020 14:59:38

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form (2)
Generated On: 10 Jun 2021 09:47:59
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 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:56:19
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 14:38:51
User entered '1'	(b) (4), (b) (6)	29 Dec 2020 14:59:38

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:56:57
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'USA-US113-2020-MRNA-1273-P301000015'	System	22 Dec 2020 20:51:57

FDA-CBER-2022-1614-3182422

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:56:55
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'Yes (Y)'	System	22 Dec 2020 20:51:57

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:56:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'No (N)'	System	22 Dec 2020 20:51:57

FDA-CBER-2022-1614-3182424

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:56:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'No (N)'	System	22 Dec 2020 20:51:57

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:57:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'Yes (Y)'	System	22 Dec 2020 20:51:57

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:57:03
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'No (N)'	System	22 Dec 2020 20:51:57

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:57:06
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'No (N)'	System	22 Dec 2020 20:51:57

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:57:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'No (N)'	System	22 Dec 2020 20:51:57

FDA-CBER-2022-1614-3182429

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:57:09
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'Priyantha'	System	22 Dec 2020 20:51:57

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:57:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'Wijewardane'	System	22 Dec 2020 20:51:57

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:11:21
User signature succeeded.	Priyantha Wijewardane (b) (4)	13 Apr 2021 01:07:27
User entered '9601 Baptist Health Drive, Medical Tower1, Ste 800'	Lauren Evans (b) (4)	12 Apr 2021 13:50:03

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:11:24
User signature succeeded.	Priyantha Wijewardane	13 Apr 2021 01:07:27
User entered 'Little Rock'	Lauren Evans (b) (4)	12 Apr 2021 13:50:03

FDA-CBER-2022-1614-3182433

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:11:27
User signature succeeded.	Priyantha Wijewardane (b) (4)	13 Apr 2021 01:07:27
User entered 'Arkansas'	Lauren Evans (b) (4)	12 Apr 2021 13:50:03

FDA-CBER-2022-1614-3182434

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:11:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	13 Apr 2021 01:07:27
User entered '72205'	Lauren Evans (b) (4)	12 Apr 2021 13:50:03

FDA-CBER-2022-1614-3182435

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:57:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 14:59:19
User entered 'US'	System	22 Dec 2020 20:53:35

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '8'	System	07 Apr 2021 15:43:57
User entered '7'	System	29 Mar 2021 16:46:59
User entered '6'	System	17 Mar 2021 15:51:25
User entered '5'	System	10 Mar 2021 16:23:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
	(b) (4)	
User entered '4'	System	06 Jan 2021 15:05:54
User entered '3'	System	30 Dec 2020 14:39:02
User entered '2'	System	29 Dec 2020 14:59:38
User entered '1'	System	22 Dec 2020 20:53:35

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form (3)
Generated On: 10 Jun 2021 09:47:59
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:56:19
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
User entered '30/Dec/2020 14:39'	(b) (4) System	30 Dec 2020 14:39:02

FDA-CBER-2022-1614-3182438

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form (3)
Generated On: 10 Jun 2021 09:47:59
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 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:56:19
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:05:42
User entered '1'	(b) (4), (b) (6)	30 Dec 2020 14:39:02

FDA-CBER-2022-1614-3182439

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:56:57
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'USA-US113-2020-MRNA-1273-P301000015'	System	22 Dec 2020 20:51:57

FDA-CBER-2022-1614-3182440

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:56:55
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'Yes (Y)'	System	22 Dec 2020 20:51:57

FDA-CBER-2022-1614-3182441

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:56:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'No (N)'	System	22 Dec 2020 20:51:57

FDA-CBER-2022-1614-3182442

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:56:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'No (N)'	System	22 Dec 2020 20:51:57

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:57:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'Yes (Y)'	System	22 Dec 2020 20:51:57

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:57:03
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'No (N)'	System	22 Dec 2020 20:51:57

FDA-CBER-2022-1614-3182445

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:57:06
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'No (N)'	System	22 Dec 2020 20:51:57

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:57:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'No (N)'	System	22 Dec 2020 20:51:57

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:57:09
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'Priyantha'	System	22 Dec 2020 20:51:57

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:57:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'Wijewardane'	System	22 Dec 2020 20:51:57

FDA-CBER-2022-1614-3182449

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:11:21
User signature succeeded.	Priyantha Wijewardane (b) (4)	13 Apr 2021 01:07:27
User entered '9601 Baptist Health Drive, Medical Tower1, Ste 800'	Lauren Evans (b) (4)	12 Apr 2021 13:50:03

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:11:24
User signature succeeded.	Priyantha Wijewardane	13 Apr 2021 01:07:27
User entered 'Little Rock'	Lauren Evans (b) (4)	12 Apr 2021 13:50:03

FDA-CBER-2022-1614-3182451

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:11:27
User signature succeeded.	Priyantha Wijewardane (b) (4)	13 Apr 2021 01:07:27
User entered 'Arkansas'	Lauren Evans (b) (4)	12 Apr 2021 13:50:03

FDA-CBER-2022-1614-3182452

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:11:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	13 Apr 2021 01:07:27
User entered '72205'	Lauren Evans (b) (4)	12 Apr 2021 13:50:03

FDA-CBER-2022-1614-3182453

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:57:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 14:59:19
User entered 'US'	System	22 Dec 2020 20:53:35

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '8'	System	07 Apr 2021 15:43:57
User entered '7'	System	29 Mar 2021 16:46:59
User entered '6'	System	17 Mar 2021 15:51:25
User entered '5'	System	10 Mar 2021 16:23:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
	(b) (4)	
User entered '4'	System	06 Jan 2021 15:05:54
User entered '3'	System	30 Dec 2020 14:39:02
User entered '2'	System	29 Dec 2020 14:59:38
User entered '1'	System	22 Dec 2020 20:53:35

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form (4)
Generated On: 10 Jun 2021 09:47:59
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:56:19
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
User entered '06/Jan/2021 15:05'	(b) (4) System	06 Jan 2021 15:05:54

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form (4)
Generated On: 10 Jun 2021 09:47:59
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 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:56:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 16:23:44
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
User entered '1'	(b) (4), (b) (6)	06 Jan 2021 15:05:54

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:56:57
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'USA-US113-2020-MRNA-1273-P301000015'	System	22 Dec 2020 20:51:57

FDA-CBER-2022-1614-3182458

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:56:55
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'Yes (Y)'	System	22 Dec 2020 20:51:57

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:56:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'No (N)'	System	22 Dec 2020 20:51:57

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:56:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'No (N)'	System	22 Dec 2020 20:51:57

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:57:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'Yes (Y)'	System	22 Dec 2020 20:51:57

FDA-CBER-2022-1614-3182462

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:57:03
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'No (N)'	System	22 Dec 2020 20:51:57

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:57:06
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'No (N)'	System	22 Dec 2020 20:51:57

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:57:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'No (N)'	System	22 Dec 2020 20:51:57

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:57:09
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'Priyantha'	System	22 Dec 2020 20:51:57

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:57:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'Wijewardane'	System	22 Dec 2020 20:51:57

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:11:21
User signature succeeded.	Priyantha Wijewardane (b) (4)	13 Apr 2021 01:07:27
User entered '9601 Baptist Health Drive, Medical Tower1, Ste 800'	Lauren Evans (b) (4)	12 Apr 2021 13:50:03

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:11:24
User signature succeeded.	Priyantha Wijewardane	13 Apr 2021 01:07:27
User entered 'Little Rock'	Lauren Evans (b) (4)	12 Apr 2021 13:50:03

FDA-CBER-2022-1614-3182469

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:11:27
User signature succeeded.	Priyantha Wijewardane	13 Apr 2021 01:07:27
User entered 'Arkansas'	Lauren Evans (b) (4)	12 Apr 2021 13:50:03

FDA-CBER-2022-1614-3182470

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:11:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	13 Apr 2021 01:07:27
User entered '72205'	Lauren Evans (b) (4)	12 Apr 2021 13:50:03

FDA-CBER-2022-1614-3182471

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:57:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:59:19
User entered 'US'	System	22 Dec 2020 20:53:35

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '8'	System	07 Apr 2021 15:43:57
User entered '7'	System	29 Mar 2021 16:46:59
User entered '6'	System	17 Mar 2021 15:51:25
User entered '5'	System	10 Mar 2021 16:23:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
	(b) (4)	
User entered '4'	System	06 Jan 2021 15:05:54
User entered '3'	System	30 Dec 2020 14:39:02
User entered '2'	System	29 Dec 2020 14:59:38
User entered '1'	System	22 Dec 2020 20:53:35

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form (5)
Generated On: 10 Jun 2021 09:47:59
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:56:19
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:22:02
User entered '10/Mar/2021 11:23'	(b) (4) System	10 Mar 2021 16:23:40

FDA-CBER-2022-1614-3182474

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form (5)
Generated On: 10 Jun 2021 09:47:59
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 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:56:19
User signature succeeded.	Priyantha Wijewardane	12 Mar 2021 16:22:02
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 16:23:44
User entered '1'	(b) (4), (b) (6)	10 Mar 2021 16:23:40

FDA-CBER-2022-1614-3182475

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:56:57
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'USA-US113-2020-MRNA-1273-P301000015'	System	22 Dec 2020 20:51:57

FDA-CBER-2022-1614-3182476

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:56:55
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'Yes (Y)'	System	22 Dec 2020 20:51:57

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:56:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'No (N)'	System	22 Dec 2020 20:51:57

FDA-CBER-2022-1614-3182478

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:56:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'No (N)'	System	22 Dec 2020 20:51:57

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:57:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'Yes (Y)'	System	22 Dec 2020 20:51:57

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:57:03
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'No (N)'	System	22 Dec 2020 20:51:57

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:57:06
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'No (N)'	System	22 Dec 2020 20:51:57

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:57:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'No (N)'	System	22 Dec 2020 20:51:57

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:57:09
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'Priyantha'	System	22 Dec 2020 20:51:57

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:57:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'Wijewardane'	System	22 Dec 2020 20:51:57

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:11:21
User signature succeeded.	Priyantha Wijewardane	13 Apr 2021 01:07:27
User entered '9601 Baptist Health Drive, Medical Tower1, Ste 800'	Lauren Evans (b) (4)	12 Apr 2021 13:50:03

FDA-CBER-2022-1614-3182486

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:11:24
User signature succeeded.	Priyantha Wijewardane (b) (4)	13 Apr 2021 01:07:27
User entered 'Little Rock'	Lauren Evans (b) (4)	12 Apr 2021 13:50:03

FDA-CBER-2022-1614-3182487

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:11:27
User signature succeeded.	Priyantha Wijewardane (b) (4)	13 Apr 2021 01:07:27
User entered 'Arkansas'	Lauren Evans (b) (4)	12 Apr 2021 13:50:03

FDA-CBER-2022-1614-3182488

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:11:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	13 Apr 2021 01:07:27
User entered '72205'	Lauren Evans (b) (4)	12 Apr 2021 13:50:03

FDA-CBER-2022-1614-3182489

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:57:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:59:19
User entered 'US'	System	22 Dec 2020 20:53:35

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '8'	System	07 Apr 2021 15:43:57
User entered '7'	System	29 Mar 2021 16:46:59
User entered '6'	System	17 Mar 2021 15:51:25
User entered '5'	System	10 Mar 2021 16:23:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
	(b) (4)	
User entered '4'	System	06 Jan 2021 15:05:54
User entered '3'	System	30 Dec 2020 14:39:02
User entered '2'	System	29 Dec 2020 14:59:38
User entered '1'	System	22 Dec 2020 20:53:35

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form (6)
Generated On: 10 Jun 2021 09:47:59
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:56:19
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:27:57
User entered '17/Mar/2021 11:51'	(b) (4) System	17 Mar 2021 15:51:25

FDA-CBER-2022-1614-3182492

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form (6)
Generated On: 10 Jun 2021 09:47:59
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 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:56:19
Reviewed for Safety.	(b) (4), (b) (6)	29 Mar 2021 16:46:44
User signature succeeded.	Priyantha Wijewardane	17 Mar 2021 20:27:57
User entered '1'	(b) (4), (b) (6)	17 Mar 2021 15:51:25

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:56:57
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'USA-US113-2020-MRNA-1273-P301000015'	System	22 Dec 2020 20:51:57

FDA-CBER-2022-1614-3182494

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:56:55
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'Yes (Y)'	System	22 Dec 2020 20:51:57

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:56:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'No (N)'	System	22 Dec 2020 20:51:57

FDA-CBER-2022-1614-3182496

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:56:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'No (N)'	System	22 Dec 2020 20:51:57

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:57:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'Yes (Y)'	System	22 Dec 2020 20:51:57

FDA-CBER-2022-1614-3182498

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:57:03
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'No (N)'	System	22 Dec 2020 20:51:57

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:57:06
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'No (N)'	System	22 Dec 2020 20:51:57

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:57:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'No (N)'	System	22 Dec 2020 20:51:57

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:57:09
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'Priyantha'	System	22 Dec 2020 20:51:57

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:57:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'Wijewardane'	System	22 Dec 2020 20:51:57

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:11:21
User signature succeeded.	Priyantha Wijewardane	13 Apr 2021 01:07:27
User entered '9601 Baptist Health Drive, Medical Tower1, Ste 800'	Lauren Evans (b) (4)	12 Apr 2021 13:50:03

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:11:24
User signature succeeded.	Priyantha Wijewardane	13 Apr 2021 01:07:27
User entered 'Little Rock'	Lauren Evans (b) (4)	12 Apr 2021 13:50:03

FDA-CBER-2022-1614-3182505

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:11:27
User signature succeeded.	Priyantha Wijewardane	13 Apr 2021 01:07:27
User entered 'Arkansas'	Lauren Evans (b) (4)	12 Apr 2021 13:50:03

FDA-CBER-2022-1614-3182506

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:11:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	13 Apr 2021 01:07:27
User entered '72205'	Lauren Evans (b) (4)	12 Apr 2021 13:50:03

FDA-CBER-2022-1614-3182507

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:57:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:59:19
User entered 'US'	System	22 Dec 2020 20:53:35

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '8'	System	07 Apr 2021 15:43:57
User entered '7'	System	29 Mar 2021 16:46:59
User entered '6'	System	17 Mar 2021 15:51:25
User entered '5'	System	10 Mar 2021 16:23:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
	(b) (4)	
User entered '4'	System	06 Jan 2021 15:05:54
User entered '3'	System	30 Dec 2020 14:39:02
User entered '2'	System	29 Dec 2020 14:59:38
User entered '1'	System	22 Dec 2020 20:53:35

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form (7)
Generated On: 10 Jun 2021 09:47:59
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:56:19
User signature succeeded.	Priyantha Wijewardane	31 Mar 2021 14:20:26
User entered '29/Mar/2021 11:46'	(b) (4) System	29 Mar 2021 16:46:59

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form (7)
Generated On: 10 Jun 2021 09:47:59
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 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:56:19
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 15:43:34
User signature succeeded.	Priyantha Wijewardane	31 Mar 2021 14:20:26
User entered '1'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:46:59

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:56:57
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'USA-US113-2020-MRNA-1273-P301000015'	System	22 Dec 2020 20:51:57

FDA-CBER-2022-1614-3182512

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:56:55
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'Yes (Y)'	System	22 Dec 2020 20:51:57

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:56:53
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'No (N)'	System	22 Dec 2020 20:51:57

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:56:59
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'No (N)'	System	22 Dec 2020 20:51:57

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:57:00
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'Yes (Y)'	System	22 Dec 2020 20:51:57

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:57:03
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'No (N)'	System	22 Dec 2020 20:51:57

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:57:06
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'No (N)'	System	22 Dec 2020 20:51:57

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:57:08
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'No (N)'	System	22 Dec 2020 20:51:57

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:57:09
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'Priyantha'	System	22 Dec 2020 20:51:57

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:57:11
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:53:21
User entered 'Wijewardane'	System	22 Dec 2020 20:51:57

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:11:21
User signature succeeded.	Priyantha Wijewardane (b) (4)	13 Apr 2021 01:07:27
User entered '9601 Baptist Health Drive, Medical Tower1, Ste 800'	Lauren Evans (b) (4)	12 Apr 2021 13:50:03

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:11:24
User signature succeeded.	Priyantha Wijewardane	13 Apr 2021 01:07:27
User entered 'Little Rock'	Lauren Evans (b) (4)	12 Apr 2021 13:50:03

FDA-CBER-2022-1614-3182523

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:11:27
User signature succeeded.	Priyantha Wijewardane (b) (4)	13 Apr 2021 01:07:27
User entered 'Arkansas'	Lauren Evans (b) (4)	12 Apr 2021 13:50:03

FDA-CBER-2022-1614-3182524

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 15:11:29
User signature succeeded.	Priyantha Wijewardane (b) (4)	13 Apr 2021 01:07:27
User entered '72205'	Lauren Evans (b) (4)	12 Apr 2021 13:50:03

FDA-CBER-2022-1614-3182525

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	08 Mar 2021 20:57:14
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 14:59:19
User entered 'US'	System	22 Dec 2020 20:53:35

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form
Generated On: 10 Jun 2021 09:47:59
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
User entered '8'	System	07 Apr 2021 15:43:57
User entered '7'	System	29 Mar 2021 16:46:59
User entered '6'	System	17 Mar 2021 15:51:25
User entered '5'	System	10 Mar 2021 16:23:40
User signature succeeded.	Priyantha Wijewardane	12 Feb 2021 19:15:12
	(b) (4)	
User entered '4'	System	06 Jan 2021 15:05:54
User entered '3'	System	30 Dec 2020 14:39:02
User entered '2'	System	29 Dec 2020 14:59:38
User entered '1'	System	22 Dec 2020 20:53:35

US3752259
Folder: SAE USA-US113-2020-MRNA-1273-P301000015
Form: Safety Report Form (8)
Generated On: 10 Jun 2021 09:47:59
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:56:19
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:41:31
User entered '07/Apr/2021 10:43'	(b) (4) System	07 Apr 2021 15:43:57

FDA-CBER-2022-1614-3182528

US3752259

Folder: SAE USA-US113-2020-MRNA-1273-P301000015

Form: Safety Report Form (8)

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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 19:30:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:56:19
User signature succeeded.	Priyantha Wijewardane	08 Apr 2021 13:41:31
User entered '1'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:43:57