US3012098 (Prod: Benchmark Research-Austin)

Generated By: KC Joubran

Generated On: 09 Jun 2021 14:54:12

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US3012098
Form: Participant Creation
Data signed: (b) (4) **05 Mar 2021 19:09:31**
Generated On: 09 Jun 2021 14:54:12

Participant ID	US3012098

mRNA-1273-P301 Completion Guidelines

FDA-CBER-2022-1614-0003899

US3012098
Folder: Screening
Form: Visit Date
Data signed: (b) (4) **05 Mar 2021 19:09:35**
Generated On: 09 Jun 2021 14:54:12

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	10 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	SCRN

FDA-CBER-2022-1614-0003900

US3012098
Folder: Screening
Form: Demographics
Data signed: (b) (4) **05 Mar 2021 19:09:34**
Generated On: 09 Jun 2021 14:54:12

Date of Birth (MMM yyyy)	(b) (6) 1959
Age	60
Age Units	YEARS
Age (Derived)	60
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

US3012098
Folder: Screening
Form: Enrollment
Data signed: (b) (4) **05 Mar 2021 19:09:34**
Generated On: 09 Jun 2021 14:54:12

Date of Informed Consent *(dd MMM yyyy)*	10 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-2022-1614-0003902

US3012098
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Data signed: (b) (4) **05 Mar 2021 19:09:34**
Generated On: 09 Jun 2021 14:54:12

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

FDA-CBER-2022-1614-0003903

US3012098
Folder: Screening
Form: Medical History Summary
Data signed: (b) (4) **05 Mar 2021 19:09:35**
Generated On: 09 Jun 2021 14:54:12

Were any significant conditions reported?	Yes ■ No ☐

FDA-CBER-2022-1614-0003904

US3012098
Folder: Screening
Form: Medical History (1)
Data signed: (b) (4) **05 Mar 2021 19:09:34**
Generated On: 09 Jun 2021 14:54:12

Condition	LYRICA ALLERGY
Start date (dd MMM yyyy)	UN UNK 1999
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 1999
Start Year (derived)	1999
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-0003905

US3012098
Folder: Screening
Form: Medical History (2)
Data signed: (b) (4) **05 Mar 2021 19:09:34**
Generated On: 09 Jun 2021 14:54:12

Condition	LITHIUM ALLERGY
Start date (dd MMM yyyy)	UN UNK 1999
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 1999
Start Year (derived)	1999
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-0003906

US3012098
Folder: Screening
Form: Medical History (3)
Data signed: (b) (4) **05 Mar 2021 19:09:34**
Generated On: 09 Jun 2021 14:54:12

Condition	KEFLEX ALLERGY
Start date (dd MMM yyyy)	UN UNK 1999
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 1999
Start Year (derived)	1999
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-0003907

US3012098
Folder: Screening
Form: Medical History (4)
Data signed: (b) (4) **05 Mar 2021 19:09:34**
Generated On: 09 Jun 2021 14:54:12

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

US3012098
Folder: Screening
Form: Medical History (5)
Data signed: (b) (4) **05 Mar 2021 19:09:34**
Generated On: 09 Jun 2021 14:54:12

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

FDA-CBER-2022-1614-0003909

US3012098
Folder: Screening
Form: Medical History (6)
Data signed: (b) (4) **05 Mar 2021 19:09:34**
Generated On: 09 Jun 2021 14:54:12

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

FDA-CBER-2022-1614-0003910

US3012098
Folder: Screening
Form: Medical History (7)
Data signed: (b) (4) **05 Mar 2021 19:09:34**
Generated On: 09 Jun 2021 14:54:12

Condition	DIVERTICULITIS
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)	

US3012098
Folder: Screening
Form: Medical History (8)
Data signed: (b) (4) **05 Mar 2021 19:09:34**
Generated On: 09 Jun 2021 14:54:12

Condition	OBESITY
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)	

FDA-CBER-2022-1614-0003912

US3012098
Folder: Screening
Form: Medical History (9)
Data signed: (b) (4) **05 Mar 2021 19:09:34**
Generated On: 09 Jun 2021 14:54:12

Condition	HYPOTHYROIDISM
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)	

FDA-CBER-2022-1614-0003913

US3012098
Folder: Screening
Form: Medical History (10)
Data signed: (b) (4) **05 Mar 2021 19:09:34**
Generated On: 09 Jun 2021 14:54:12

Condition	MENOPAUSE
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes ■ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-0003914

US3012098
Folder: Screening
Form: Medical History (11)
Data signed: (b) (4) **05 Mar 2021 19:09:34**
Generated On: 09 Jun 2021 14:54:12

Condition	OVERACTIVE BLADDER
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes ■ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-0003915

US3012098
Folder: Screening
Form: Medical History (12)
Data signed: (b) (4) **05 Mar 2021 19:09:34**
Generated On: 09 Jun 2021 14:54:12

Condition	HYPERTENSION
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-2022-1614-0003916

US3012098
Folder: Screening
Form: Medical History (13)
Data signed: (b) (4) **05 Mar 2021 19:09:34**
Generated On: 09 Jun 2021 14:54:12

Condition	HYPERCHOLESTEROLEMIA
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-2022-1614-0003917

US3012098
Folder: Screening
Form: Medical History (14)
Data signed: (b) (4) **05 Mar 2021 19:09:34**
Generated On: 09 Jun 2021 14:54:12

Condition	EMPHYSEMA
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-2022-1614-0003918

US3012098
Folder: Screening
Form: Medical History (15)
Data signed: (b) (4) **05 Mar 2021 19:09:34**
Generated On: 09 Jun 2021 14:54:12

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

FDA-CBER-2022-1614-0003919

US3012098
Folder: Screening
Form: Medical History (16)
Data signed: (b) (4) **05 Mar 2021 19:09:34**
Generated On: 09 Jun 2021 14:54:12

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

FDA-CBER-2022-1614-0003920

US3012098
Folder: Screening
Form: Medical History (17)
Data signed: (b) (4) **05 Mar 2021 19:09:34**
Generated On: 09 Jun 2021 14:54:12

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

US3012098
Folder: Screening
Form: Medical History (18)
Data signed: (b) (4) **05 Mar 2021 19:09:34**
Generated On: 09 Jun 2021 14:54:12

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

FDA-CBER-2022-1614-0003922

US3012098
Folder: Screening
Form: Medical History (19)
Data signed: (b) (4) **05 Mar 2021 19:09:34**
Generated On: 09 Jun 2021 14:54:12

Condition	OSTEOARTHRITIS (LOWER BACK, LOWER NECK)
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-2022-1614-0003923

US3012098
Folder: Screening
Form: Medical History (20)
Data signed: (b) (4) **05 Mar 2021 19:09:34**
Generated On: 09 Jun 2021 14:54:12

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

FDA-CBER-2022-1614-0003924

US3012098
Folder: Screening
Form: Medical History (21)
Data signed: (b) (4) **05 Mar 2021 19:09:34**
Generated On: 09 Jun 2021 14:54:12

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

FDA-CBER-2022-1614-0003925

US3012098
Folder: Screening
Form: Medical History (22)
Data signed: (b) (4) **05 Mar 2021 19:09:34**
Generated On: 09 Jun 2021 14:54:12

Condition	UMBILICAL HERNIA
Start date (dd MMM yyyy)	UN UNK 1997
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 1997
Start Year (derived)	1997
Stop Month and Year (derived)	
Stop Year (derived)	

FDA-CBER-2022-1614-0003926

US3012098
Folder: Screening
Form: Medical History (23)
Data signed: (b) (4) **05 Mar 2021 19:09:34**
Generated On: 09 Jun 2021 14:54:12

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

FDA-CBER-2022-1614-0003927

US3012098
Folder: Screening
Form: Medical History (24)
Data signed: (b) (4) **05 Mar 2021 19:09:34**
Generated On: 09 Jun 2021 14:54:12

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

FDA-CBER-2022-1614-0003928

US3012098
Folder: Screening
Form: Medical History (25)
Data signed: (b) (4) **05 Mar 2021 19:09:34**
Generated On: 09 Jun 2021 14:54:12

Condition	DIASTOLIC CONGESTIVE HEART FAILURE
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-2022-1614-0003929

US3012098
Folder: Screening
Form: Vital Signs
Data signed: (b) (4) **05 Mar 2021 19:09:35**
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Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	10 AUG 2020
Time of assessment *(00:00-23:59)*	17:27 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 17:27
Height *(xxx.x)*	62.0 in
Weight *(xxx.x)*	182.6 lb
BMI *(xxx.x)*	33.46781 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)	

US3012098
Folder: Screening
Form: Physical Examination
Data signed: (b) (4) **05 Mar 2021 19:09:35**
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Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	10 AUG 2020

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

FDA-CBER-2022-1614-0003931

US3012098
Folder: Screening
Form: Childbearing Potential
Data signed: (b) (4) **05 Mar 2021 19:09:34**
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Date of assessment *(dd MMM yyyy)*	10 AUG 2020
Is the participant of childbearing potential?	Yes ☐ No ■
If No, what is the reason?	Surgically sterile ☐ Post-menopausal ■ Partner medically sterile ☐ Not reached age of Menarche ☐ Other ☐
If Partner medically sterile or Other, specify	
If Surgically sterile, date of surgery *(dd MMM yyyy)*	
Date of surgery unknown	False
If Post-menopausal, date of last menstruation *(dd MMM yyyy)*	UN UNK 2004
Date of last menstruation unknown	False

FDA-CBER-2022-1614-0003932

US3012098
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **05 Mar 2021 19:09:35**
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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	False
Resides in Nursing Home or Assisted Living Facility	False

FDA-CBER-2022-1614-0003933

US3012098
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **05 Mar 2021 19:09:35**
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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)	True
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

FDA-CBER-2022-1614-0003934

US3012098
Folder: Visit 1 Day 1
Form: Visit Date
Data signed: (b) (4) **05 Mar 2021 19:09:35**
Generated On: 09 Jun 2021 14:54:12

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	10 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT1

FDA-CBER-2022-1614-0003935

US3012098
Folder: Visit 1 Day 1
Form: Randomization
Data signed: (b) (4) **05 Mar 2021 19:09:35**
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What was the date of randomization? *(dd MMM yyyy)*	10 AUG 2020
What was the participant's randomization number?	143598
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-2022-1614-0003936

US3012098
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Data signed: (b) (4) **05 Mar 2021 19:09:35**
Generated On: 09 Jun 2021 14:54:12

Height	ND - Not Done
Weight	ND - Not Done

FDA-CBER-2022-1614-0003937

US3012098
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **05 Mar 2021 19:09:35**
Generated On: 09 Jun 2021 14:54:12

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)*	10 AUG 2020
Time of assessment *(00:00-23:59)*	17:27 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 17:27
Temperature *(xxx.x)*	98.4 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	92 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	88 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-0003938

US3012098
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **05 Mar 2021 19:09:35**
Generated On: 09 Jun 2021 14:54:12

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)*	10 AUG 2020
Time of assessment *(00:00-23:59)*	19:46 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 19:46
Temperature *(xxx.x)*	98.1 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	82 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	80 mmHg
Diastolic Blood Pressure units	MMHG

US3012098
Folder: Visit 1 Day 1
Form: Physical Examination
Data signed: (b) (4) **05 Mar 2021 19:09:35**
Generated On: 09 Jun 2021 14:54:12

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

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

FDA-CBER-2022-1614-0003940

US3012098
Folder: Visit 1 Day 1
Form: Exposure
Data signed: (b) (4) **05 Mar 2021 19:09:35**
Generated On: 09 Jun 2021 14:54:12

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)*	10 AUG 2020
What was the treatment time? *(00:00-23:59)*	19:13 (24 HR)
Treatment Date and Time (derived)	10 AUG 2020 19:13
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-2022-1614-0003941

US3012098
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Data signed: (b) (4) **05 Mar 2021 19:09:35**
Generated On: 09 Jun 2021 14:54:12

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	10 AUG 2020
Collection time *(00:00-23:59)*	18:06 (24 HR)
Collection date and time (derived)	10 AUG 2020 18:06

US3012098
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **05 Mar 2021 19:09:35**
Generated On: 09 Jun 2021 14:54:12

Collection date *(dd MMM yyyy)*			10 AUG 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	18:33	10 AUG 2020 18:33
Nasopharyngeal Swab 2	No		

FDA-CBER-2022-1614-0003943

US3012098
Folder: Visit 1 Day 1
Form: Continuing
Data signed: (b) (4) **05 Mar 2021 19:09:35**
Generated On: 09 Jun 2021 14:54:12

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

FDA-CBER-2022-1614-0003944

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**	98.1 °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	10 AUG 2020 19:46
PC Open Date & Time	10 AUG 2020 19:33
PC Close Date & Time	10 AUG 2020 22:03

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ☐ No ☐
Please record your **TEMPERATURE in °F**	_____
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ☐
Please confirm reason for pain or fever medication (may select more than one):	
To **TREAT** pain or fever that has already occurred	_____
To **PREVENT** pain or fever from occurring	_____
PC Time Stamp	_____
PC Open Date & Time	10 AUG 2020 22:58
PC Close Date & Time	11 AUG 2020 11:59

US3012098
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:54:12

TIMEPOINT	DAY 2

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.7 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	11 AUG 2020 13:36
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3012098
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:54:12

TIMEPOINT	DAY 3

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ☒ No ☐
Please record your **TEMPERATURE in °F**	98.3 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ☒
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	12 AUG 2020 17:31
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

FDA-CBER-2022-1614-0003948

US3012098
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 14:54:12

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**	97.0 °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	13 AUG 2020 19:04
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

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	14 AUG 2020 18:13
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

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**	96.8 °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	15 AUG 2020 18:43
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3012098
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:54:12

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**	96.8 °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	16 AUG 2020 23:45
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3012098
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:54:12

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	10 AUG 2020 19:47
PC Open Date & Time	10 AUG 2020 19:33
PC Close Date & Time	10 AUG 2020 22:03

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ☐ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ☐
Please record - **REDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site redness with the ruler provided.	_____
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ☐
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site swelling/hardness with the ruler provided.	_____
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ☐ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	_____
PC Open Date & Time	10 AUG 2020 22:58
PC Close Date & Time	11 AUG 2020 11:59

US3012098
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:54:12

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	11 AUG 2020 13:36
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3012098
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 14:54:12

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	12 AUG 2020 17:32
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

FDA-CBER-2022-1614-0003956

US3012098
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:54:12

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	13 AUG 2020 19:04
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3012098
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:54:12

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	14 AUG 2020 18:14
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3012098
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:54:12

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	15 AUG 2020 18:44
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3012098
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:54:12

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	16 AUG 2020 23:46
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

FDA-CBER-2022-1614-0003960

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 ☐

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:54:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	10 AUG 2020 19:47
PC Open Date & Time	10 AUG 2020 19:33
PC Close Date & Time	10 AUG 2020 22:03

FDA-CBER-2022-1614-0003962

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 ☐

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:54:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☐ Yes ☐
PC Time stamp	
PC Open Date & Time	10 AUG 2020 22:58
PC Close Date & Time	11 AUG 2020 11:59

FDA-CBER-2022-1614-0003964

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:54:12

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-2022-1614-0003965

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:54:12

	Yes ☐
PC Time stamp	11 AUG 2020 13:37
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

FDA-CBER-2022-1614-0003966

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:54:12

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 ■

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:54:12

	Yes ☐
PC Time stamp	12 AUG 2020 17:33
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

FDA-CBER-2022-1614-0003968

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:54:12

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-2022-1614-0003969

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:54:12

	Yes ☐
PC Time stamp	13 AUG 2020 19:05
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:54:12

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-2022-1614-0003971

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:54:12

	Yes ☐
PC Time stamp	14 AUG 2020 18:15
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

FDA-CBER-2022-1614-0003972

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:54:12

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-2022-1614-0003973

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:54:12

	Yes
PC Time stamp	15 AUG 2020 18:45
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:54:12

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-2022-1614-0003975

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:54:12

	Yes ☐
PC Time stamp	16 AUG 2020 23:47
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

FDA-CBER-2022-1614-0003976

US3012098
Folder: Safety Call Day 8 (1)
Form: Safety Call
Data signed: (b) (4) **05 Mar 2021 19:09:34**
Generated On: 09 Jun 2021 14:54:12

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	19 AUG 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

US3012098
Folder: Safety Call Day 8 (1)
Form: Continuing
Data signed: (b) (4) **05 Mar 2021 19:09:34**
Generated On: 09 Jun 2021 14:54:12

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

FDA-CBER-2022-1614-0003978

US3012098
Folder: Safety Call Day 15 (1)
Form: Safety Call
Data signed: (b) (4) **05 Mar 2021 19:09:34**
Generated On: 09 Jun 2021 14:54:12

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	26 AUG 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

FDA-CBER-2022-1614-0003979

US3012098
Folder: Safety Call Day 15 (1)
Form: Continuing
Data signed: (b) (4) **05 Mar 2021 19:09:34**
Generated On: 09 Jun 2021 14:54:12

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

FDA-CBER-2022-1614-0003980

US3012098
Folder: Safety Call Day 22 (1)
Form: Safety Call
Data signed: (b) (4) **05 Mar 2021 19:09:34**
Generated On: 09 Jun 2021 14:54:12

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	1 SEP 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

US3012098
Folder: Safety Call Day 22 (1)
Form: Continuing
Data signed: (b) (4) **05 Mar 2021 19:09:34**
Generated On: 09 Jun 2021 14:54:12

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

FDA-CBER-2022-1614-0003982

US3012098
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Data signed: (b) (4) **05 Mar 2021 19:09:35**
Generated On: 09 Jun 2021 14:54:12

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	08 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT2

FDA-CBER-2022-1614-0003983

US3012098
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **05 Mar 2021 19:09:35**
Generated On: 09 Jun 2021 14:54:12

Timepoint	Pre-Dose ■ Post-Dose ☐
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	08 SEP 2020
Time of assessment *(00:00-23:59)*	07:23 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 07:23
Temperature *(xxx.x)*	97.8 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	86 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	85 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-0003984

US3012098
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **05 Mar 2021 19:09:35**
Generated On: 09 Jun 2021 14:54:12

Timepoint	Pre-Dose ☐ Post-Dose ■
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	08 SEP 2020
Time of assessment *(00:00-23:59)*	09:24 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 09:24
Temperature *(xxx.x)*	97.7 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	80 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	83 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-0003985

US3012098
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Data signed: (b) (4) **05 Mar 2021 19:09:35**
Generated On: 09 Jun 2021 14:54:12

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	08 SEP 2020

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

FDA-CBER-2022-1614-0003986

US3012098
Folder: Visit 2 Day 29 (1)
Form: Exposure
Data signed: (b) (4) **05 Mar 2021 19:09:35**
Generated On: 09 Jun 2021 14:54:12

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)*	08 SEP 2020
What was the treatment time? *(00:00-23:59)*	08:44 (24 HR)
Treatment Date and Time (derived)	08 SEP 2020 08:44
Which arm was used to give treatment?	Left Arm ■ Right Arm ☐
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

FDA-CBER-2022-1614-0003987

US3012098
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **05 Mar 2021 19:09:35**
Generated On: 09 Jun 2021 14:54:12

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	08 SEP 2020
Collection time *(00:00-23:59)*	07:55 (24 HR)
Collection date and time (derived)	08 SEP 2020 07:55

FDA-CBER-2022-1614-0003988

US3012098
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **05 Mar 2021 19:09:35**
Generated On: 09 Jun 2021 14:54:12

Collection date *(dd MMM yyyy)*			08 SEP 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	07:42	08 SEP 2020 07:42
Nasopharyngeal Swab 2	No		

FDA-CBER-2022-1614-0003989

US3012098
Folder: Visit 2 Day 29 (1)
Form: Continuing
Data signed: (b) (4) **05 Mar 2021 19:09:35**
Generated On: 09 Jun 2021 14:54:12

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

FDA-CBER-2022-1614-0003990

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 14:54:12

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.7 °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	08 SEP 2020 09:21
PC Open Date & Time	08 SEP 2020 09:04
PC Close Date & Time	08 SEP 2020 11:34

TIMEPOINT	DAY 1, AFTER VACCINATION (AT HOME)

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	98.2 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	08 SEP 2020 19:45
PC Open Date & Time	08 SEP 2020 12:29
PC Close Date & Time	09 SEP 2020 11:59

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:54:12

TIMEPOINT	DAY 2

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ☒ No ☐
Please record your **TEMPERATURE in °F**	98.8 °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	09 SEP 2020 17:52
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:54:12

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**	97.1 °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	10 SEP 2020 19:54
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

FDA-CBER-2022-1614-0003994

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 14:54:12

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**	98.6 °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	11 SEP 2020 19:24
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:54:12

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**	96.8 °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	12 SEP 2020 21:21
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:54:12

TIMEPOINT	DAY 6

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

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

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

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

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

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

Was **TEMPERATURE** taken?	Yes ■ No ☐
Please record your **TEMPERATURE in °F**	97.6 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	13 SEP 2020 17:40
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:54:12

TIMEPOINT	DAY 7

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

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

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

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

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

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

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

US3012098
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:54:12

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	08 SEP 2020 09:21
PC Open Date & Time	08 SEP 2020 09:04
PC Close Date & Time	08 SEP 2020 11:34

FDA-CBER-2022-1614-0003999

US3012098
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:54:12

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	08 SEP 2020 19:46
PC Open Date & Time	08 SEP 2020 12:29
PC Close Date & Time	09 SEP 2020 11:59

US3012098
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:54:12

TIMEPOINT	DAY 2
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ☐ Does not interfere with activity ■ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ■
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ■ No ☐
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site swelling/hardness with the ruler provided.	30
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	09 SEP 2020 17:55
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

FDA-CBER-2022-1614-0004001

US3012098
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 14:54:12

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	10 SEP 2020 19:55
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3012098
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:54:12

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	11 SEP 2020 19:24
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3012098
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:54:12

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	12 SEP 2020 21:22
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3012098
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:54:12

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	13 SEP 2020 17:40
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3012098
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:54:12

TIMEPOINT	DAY 7
Please record - **PAIN AT INJECTION SITE.** Please select one response below	None ☐ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
Is there any **REDNESS AT INJECTION SITE**?	Yes ☐ No ☐
Please record - **REDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site redness with the ruler provided.	_____
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?	Yes ☐ No ☐
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site swelling/hardness with the ruler provided.	_____
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.** Please select one response below	None ☐ Does not interfere with activity ☐ Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity ☐ Any use of prescription pain reliever or prevents daily activity ☐
PC Time Stamp	_____
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

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

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:54:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	08 SEP 2020 09:22
PC Open Date & Time	08 SEP 2020 09:04
PC Close Date & Time	08 SEP 2020 11:34

FDA-CBER-2022-1614-0004008

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:54:12

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-2022-1614-0004009

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:54:12

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	08 SEP 2020 19:47
PC Open Date & Time	08 SEP 2020 12:29
PC Close Date & Time	09 SEP 2020 11:59

FDA-CBER-2022-1614-0004010

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:54:12

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 ■

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:54:12

	Yes
PC Time stamp	09 SEP 2020 17:56
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

FDA-CBER-2022-1614-0004012

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:54:12

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 ■

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:54:12

	Yes
PC Time stamp	10 SEP 2020 19:55
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

FDA-CBER-2022-1614-0004014

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 ■

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:54:12

	Yes ☐
PC Time stamp	11 SEP 2020 19:25
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

FDA-CBER-2022-1614-0004016

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 ■

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:54:12

	Yes ☐
PC Time stamp	12 SEP 2020 21:23
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:54:12

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 ■

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:54:12

	Yes
PC Time stamp	13 SEP 2020 17:41
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

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

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

US3012098
Folder: Safety Call Day 36 (1)
Form: Safety Call
Data signed: (b) (4) **05 Mar 2021 19:09:34**
Generated On: 09 Jun 2021 14:54:12

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	17 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-2022-1614-0004023

US3012098
Folder: Safety Call Day 36 (1)
Form: Continuing
Data signed: (b) (4) **05 Mar 2021 19:09:34**
Generated On: 09 Jun 2021 14:54:12

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

FDA-CBER-2022-1614-0004024

US3012098
Folder: Safety Call Day 43 (1)
Form: Safety Call
Data signed: (b) (4) **05 Mar 2021 19:09:34**
Generated On: 09 Jun 2021 14:54:12

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	23 SEP 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

US3012098
Folder: Safety Call Day 43 (1)
Form: Continuing
Data signed: (b) (4) **05 Mar 2021 19:09:34**
Generated On: 09 Jun 2021 14:54:12

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

FDA-CBER-2022-1614-0004026

US3012098
Folder: Safety Call Day 50 (1)
Form: Safety Call
Data signed: (b) (4) **05 Mar 2021 19:09:34**
Generated On: 09 Jun 2021 14:54:12

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	1 OCT 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

US3012098
Folder: Safety Call Day 50 (1)
Form: Continuing
Data signed: (b) (4) **05 Mar 2021 19:09:34**
Generated On: 09 Jun 2021 14:54:12

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

FDA-CBER-2022-1614-0004028

US3012098
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Data signed: (b) (4) **05 Mar 2021 19:09:35**
Generated On: 09 Jun 2021 14:54:12

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	13 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT3

FDA-CBER-2022-1614-0004029

US3012098
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Data signed: (b) (4) **05 Mar 2021 19:09:35**
Generated On: 09 Jun 2021 14:54:12

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	13 OCT 2020
Time of assessment *(00:00-23:59)*	15:15 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 15:15
Temperature *(xxx.x)*	98.0 F
Route of measurement	Oral ■ Axillary ☐ Other ☐
If Other, specify	
Pulse *(xxx)*	98 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	67 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3012098
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Data signed: (b) (4) **05 Mar 2021 19:09:35**
Generated On: 09 Jun 2021 14:54:12

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	13 OCT 2020

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

FDA-CBER-2022-1614-0004031

US3012098
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **05 Mar 2021 19:09:35**
Generated On: 09 Jun 2021 14:54:12

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	13 OCT 2020
Collection time *(00:00-23:59)*	16:00 (24 HR)
Collection date and time (derived)	13 OCT 2020 16:00

US3012098
Folder: Visit 3 Day 57 (1)
Form: Continuing
Data signed: (b) (4) **05 Mar 2021 19:09:35**
Generated On: 09 Jun 2021 14:54:12

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

FDA-CBER-2022-1614-0004033

US3012098
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12

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	14 OCT 2020 18:09:07
Patient Cloud Open Date & Time	10 OCT 2020 00:01
Patient Cloud Close Date & Time	14 OCT 2020 23:59

US3012098
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12

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	17 OCT 2020 02:45:18
Patient Cloud Open Date & Time	17 OCT 2020 00:01
Patient Cloud Close Date & Time	21 OCT 2020 23:59

FDA-CBER-2022-1614-0004035

US3012098
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12

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	28 OCT 2020 19:49:41
Patient Cloud Open Date & Time	24 OCT 2020 00:01
Patient Cloud Close Date & Time	28 OCT 2020 23:59

US3012098
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 NOV 2020 18:00:56
Patient Cloud Open Date & Time	07 NOV 2020 00:01
Patient Cloud Close Date & Time	11 NOV 2020 23:59

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3012098
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	14 NOV 2020 00:01
Patient Cloud Close Date & Time	18 NOV 2020 23:59

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

US3012098
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	18 NOV 2020 00:01
Patient Cloud Close Date & Time	22 NOV 2020 23:59

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

US3012098
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	25 NOV 2020 00:01
Patient Cloud Close Date & Time	29 NOV 2020 23:59

US3012098
Folder: Cosmetic Injections and Dermal Fillers
Form: Cosmetic Injection_ Dermal Filler eDiary
Generated On: 09 Jun 2021 14:54:12

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-2022-1614-0004044

US3012098
Folder: Safety Call Day 85 (1)
Form: Safety Call
Data signed: (b) (4) **05 Mar 2021 19:09:34**
Generated On: 09 Jun 2021 14:54:12

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	03 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-2022-1614-0004045

US3012098
Folder: Safety Call Day 85 (1)
Form: Continuing
Data signed: (b) (4) **05 Mar 2021 19:09:34**
Generated On: 09 Jun 2021 14:54:12

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

FDA-CBER-2022-1614-0004046

US3012098
Folder: Covid-19 Assessment (1)
Form: COVID-19 Contact
Generated On: 09 Jun 2021 14:54:12

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled ☐ Clinical Visit - Unscheduled ☐ Safety Call ☐ Convalescent Tele-visit ☐
Has the subject reported symptoms of SARS-COV-2?	Yes ☐ No ☐

FDA-CBER-2022-1614-0004047

US3012098
Folder: Covid-19 Assessment (1)
Form: Generate Next COVID-19 Assessment
Generated On: 09 Jun 2021 14:54:12

Generate Next COVID-19 Assessment	Yes ☐ No ☐

FDA-CBER-2022-1614-0004048

US3012098
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:54:12

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

FDA-CBER-2022-1614-0004049

US3012098
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 09 Jun 2021 14:54:12

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

FDA-CBER-2022-1614-0004050

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

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

US3012098
Folder: Adverse Events
Form: Adverse Events Summary
Data signed: (b) (4) **05 Mar 2021 19:09:32**
Generated On: 09 Jun 2021 14:54:12

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

If Yes, enter details on the Adverse Events form.

US3012098
Folder: Adverse Events
Form: Adverse Events (1)
Data signed: (b) (4) **12 Mar 2021 19:15:26**
Generated On: 09 Jun 2021 14:54:12

AEID	USA-US006-2020-MRNA-1273-P30 1000002
Adverse event	COLITIS
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)*	24 SEP 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ■
If not Ongoing, end date *(dd MMM yyyy)*	30 SEP 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ■ Grade 4 ☐
Is the adverse event serious?	Yes ■ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date *(dd MMM yyyy)*	26 SEP 2020
Hospital Discharge Date *(dd MMM yyyy)*	12 OCT 2020
Admitted to ICU?	Yes ☐ No ■ Unknown ☐

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ■ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ■ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ■
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ■ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	

Narrative

US3012098
Folder: Adverse Events
Form: Adverse Events (1)
Data signed: (b) (4) **12 Mar 2021 19:15:26**
Generated On: 09 Jun 2021 14:54:12

	PATIENT REPORTED TO ER ON 26-SEP-2020 WITH SEVERE ABDOMINAL PAIN, GENERAL/ENTIRE AREA. WAS ADMITTED AND GIVEN UNKNOWN MEDICATIONS FOR PAIN AND SUBSEQUENTLY DIAGNOSED WITH COLITIS.
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

FDA-CBER-2022-1614-0004056

US3012098
Folder: Adverse Events
Form: Adverse Events (2)
Data signed: (b) (4) **12 Mar 2021 19:15:26**
Generated On: 09 Jun 2021 14:54:12

AEID	USA-US006-2020-MRNA-1273-P30 1000002
Adverse event	CLOSTRIDIUM DIFFICILE
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)*	29 SEP 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ■
If not Ongoing, end date *(dd MMM yyyy)*	25 OCT 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ■ Grade 4 ☐
Is the adverse event serious?	Yes ■ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date *(dd MMM yyyy)*	26 SEP 2020
Hospital Discharge Date *(dd MMM yyyy)*	12 OCT 2020
Admitted to ICU?	Yes ■ No ☐ Unknown ☐

Number of Days in ICU	5
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ■ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ■ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ■
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ■ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUBJECT WAS ADMITTED TO HOSPITAL ON 29-SEP-2020 DUE TO ABDOMINAL PAIN, WAS DIAGNOSED WITH C-DIFF 5 DAYS LATER, TREATED AND RELEASED ON 12-OCT-2020.
Serious Adverse Event Derived (CSA Programming Field Ony)	1

US3012098
Folder: Adverse Events
Form: Adverse Events (2)
Data signed: (b) (4) **12 Mar 2021 19:15:26**
Generated On: 09 Jun 2021 14:54:12

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

US3012098
Folder: Adverse Events
Form: Adverse Events (3)
Data signed: (b) (4) **12 Mar 2021 19:15:26**
Generated On: 09 Jun 2021 14:54:12

AEID	USA-US006-2020-MRNA-1273-P301000002
Adverse event	ACUTE HYPOXIC RESPIRATORY FAILURE
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)*	29 SEP 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ■
If not Ongoing, end date *(dd MMM yyyy)*	12 OCT 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ■
Is the adverse event serious?	Yes ■ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date *(dd MMM yyyy)*	29 SEP 2020
Hospital Discharge Date *(dd MMM yyyy)*	12 OCT 2020
Admitted to ICU?	Yes ☐ No ■ Unknown ☐

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ■ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ■ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ■
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ■ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	

Narrative

	SUBJECT REPORTED TO ER WITH ABDOMINAL PAIN. DURING COURSE OF HOSPITALIZATION, SUBJECT EXPERIENCED ACUTE HYPOXIC RESPIRATORY FAILURE. UNKNOWN WHAT DATE THIS OCCURRED OR HOW LONG IT LASTED.
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

US3012098
Folder: Adverse Events
Form: Adverse Events (4)
Data signed: (b) (4) **12 Mar 2021 19:15:26**
Generated On: 09 Jun 2021 14:54:12

AEID	USA-US006-2020-MRNA-1273-P301000002
Adverse event	EXACERBATION OF DIASTOLIC CHF
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)*	29 SEP 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ■
If not Ongoing, end date *(dd MMM yyyy)*	12 OCT 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ■ Grade 4 ☐
Is the adverse event serious?	Yes ■ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date *(dd MMM yyyy)*	29 SEP 2020
Hospital Discharge Date *(dd MMM yyyy)*	12 OCT 2020
Admitted to ICU?	Yes ☐ No ■ Unknown ☐

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ■ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ■ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ■
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ■ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	

Narrative

US3012098
Folder: Adverse Events
Form: Adverse Events (4)
Data signed: (b) (4) **12 Mar 2021 19:15:26**
Generated On: 09 Jun 2021 14:54:12

	SUBJECT REPORTED TO ER WITH ABDOMINAL PAIN. DURING COURSE OF HOSPITALIZATION, SUBJECT EXPERIENCED AN EXACERBATION OF CONGESTIVE HEART FAILURE. UNKNOWN WHAT DATE THIS OCCURRED OR HOW LONG IT LASTED.
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

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Data signed: (b) (4) **05 Mar 2021 19:09:33**
Generated On: 09 Jun 2021 14:54:12

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

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

FDA-CBER-2022-1614-0004066

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Data signed: (b) (4) **15 Apr 2021 16:35:02**
Generated On: 09 Jun 2021 14:54:12

Name of Medication	ALBUTEROL
Prophylaxis	Yes ☐ No ■
Indication	EMPHYSEMA
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 ☐

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

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Data signed: (b) (4) **15 Apr 2021 16:35:02**
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Name of Medication	ABILIFY
Prophylaxis	Yes ☐ No ■
Indication	DEPRESSION
Dose per administration	15
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

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

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Data signed: (b) (4) **15 Apr 2021 16:35:02**
Generated On: 09 Jun 2021 14:54:12

Name of Medication	ATORVASTATIN
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 ☐

	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 ■

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Data signed: (b) (4) **15 Apr 2021 16:35:02**
Generated On: 09 Jun 2021 14:54:12

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

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2000
Start date completely unknown	False
Ongoing?	Yes ■ No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	4
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Data signed: (b) (4) **15 Apr 2021 16:35:02**
Generated On: 09 Jun 2021 14:54:12

Name of Medication	DEXILANT
Prophylaxis	Yes ☐ No ■
Indication	DIVERTICULITIS
Dose per administration	60
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 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)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Data signed: (b) (4) **15 Apr 2021 16:35:02**
Generated On: 09 Jun 2021 14:54:12

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

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

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Data signed: (b) (4) **15 Apr 2021 16:35:02**
Generated On: 09 Jun 2021 14:54:12

Name of Medication	FISH OIL
Prophylaxis	Yes ■ No ☐
Indication	NUTRITIONAL SUPPLEMENT
Dose per administration	1000
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

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

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Data signed: (b) (4) **15 Apr 2021 16:35:02**
Generated On: 09 Jun 2021 14:54:12

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

	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)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ☐

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Data signed: (b) (4) **15 Apr 2021 16:35:02**
Generated On: 09 Jun 2021 14:54:12

Name of Medication	GLUCOSAMINE CHONDROITIN
Prophylaxis	Yes ■ No ☐
Indication	NUTRITIONAL SUPPLEMENT
Dose per administration	1000
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

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

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Data signed: (b) (4) **15 Apr 2021 16:35:02**
Generated On: 09 Jun 2021 14:54:12

Name of Medication	HYDROCODONE/APAP
Prophylaxis	Yes ☐ No ■
Indication	OSTEOARTHRITIS
Dose per administration	10/325
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ■ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2000
Start date completely unknown	False
Ongoing?	Yes ■ No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	4
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Data signed: (b) (4) **15 Apr 2021 16:35:02**
Generated On: 09 Jun 2021 14:54:12

Name of Medication	ASTELIN
Prophylaxis	Yes ○ No ●
Indication	EMPHYSEMA
Dose per administration	137
Dose unit	mg ○ ug ● mL ○ g ○ IU ○ tablet ○ capsule ○ puff ○ Other ○
If dose unit is Other, specify	
Frequency	once daily ○ twice daily ○ three times daily ○ four times daily ○ every other day ○ every week ○ every month ○ as needed ● once ○ unknown ○ other ○
If frequency is Other, specify	
Route of administration	Oral ○ Topical ○ Subcutaneous ○ Transdermal ○ Intraocular ○

	Intramuscular ☐
	Respiratory (Inhalation) ■
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 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)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☐

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Data signed: (b) (4) **15 Apr 2021 16:35:02**
Generated On: 09 Jun 2021 14:54:12

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

	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 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 ■

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Data signed: (b) (4) **15 Apr 2021 16:35:02**
Generated On: 09 Jun 2021 14:54:12

Name of Medication	IRON
Prophylaxis	Yes ■ No ☐
Indication	NUTRITIONAL SUPPLEMENT
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)*	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)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Data signed: (b) (4) **15 Apr 2021 16:35:02**
Generated On: 09 Jun 2021 14:54:12

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

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

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Data signed: (b) (4) **15 Apr 2021 16:35:02**
Generated On: 09 Jun 2021 14:54:12

Name of Medication	LEVOTHYROXINE
Prophylaxis	Yes ☐ No ■
Indication	HYPOTHYROIDISM
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 ☐

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

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Data signed: (b) (4) **15 Apr 2021 16:35:02**
Generated On: 09 Jun 2021 14:54:12

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

	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 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 ■

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Data signed: (b) (4) **15 Apr 2021 16:35:02**
Generated On: 09 Jun 2021 14:54:12

Name of Medication	MONTELUKAST
Prophylaxis	Yes ☐ No ■
Indication	SEASONAL ALLERGIES
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 ☐

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	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 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)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

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Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Data signed: (b) (4) **15 Apr 2021 16:35:02**
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Name of Medication	TOPIRAMATE
Prophylaxis	Yes ☐ No ■
Indication	FIBROMYALGIA
Dose per administration	100
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ■ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	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)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Data signed: (b) (4) **15 Apr 2021 16:35:02**
Generated On: 09 Jun 2021 14:54:12

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

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

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Data signed: (b) (4) **15 Apr 2021 16:35:02**
Generated On: 09 Jun 2021 14:54:12

Name of Medication	VANCOMYCIN
Prophylaxis	Yes ○ No ●
Indication	C-DIFF
Dose per administration	125
Dose unit	mg ● ug ○ mL ○ g ○ IU ○ tablet ○ capsule ○ puff ○ Other ○
If dose unit is Other, specify	
Frequency	once daily ○ twice daily ○ three times daily ○ four times daily ● every other day ○ every week ○ every month ○ as needed ○ once ○ unknown ○ other ○
If frequency is Other, specify	
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)*	29 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	22 OCT 2020
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	4
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Data signed: (b) (4) **15 Apr 2021 16:35:02**
Generated On: 09 Jun 2021 14:54:12

Name of Medication	DICYCLOMINE
Prophylaxis	Yes ☐ No ■
Indication	COLITIS (AE #1)
Dose per administration	20
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ■ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	29 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	12 OCT 2020
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	4
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Data signed: (b) (4) **15 Apr 2021 16:35:02**
Generated On: 09 Jun 2021 14:54:12

Name of Medication	ONDASETRON
Prophylaxis	Yes ☐ No ■
Indication	NAUSEA
Dose per administration	4
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ■
If frequency is Other, specify	Q6H/PRN
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)*	28 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ■ No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ☐

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Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Data signed: (b) (4) **15 Apr 2021 16:35:02**
Generated On: 09 Jun 2021 14:54:12

Name of Medication	BENZOCCINE 20%
Prophylaxis	Yes ○ No ●
Indication	CRACKED TONGUE , FEVER BLISTER
Dose per administration	1
Dose unit	mg ○ ug ○ mL ○ g ○ IU ○ tablet ○ capsule ○ puff ○ Other ●
If dose unit is Other, specify	APPLICATION
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)*	10 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ■ No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ☐

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Data signed: (b) (4) **15 Apr 2021 16:35:02**
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Name of Medication	DIMETHICONE 1.5%
Prophylaxis	Yes No
Indication	BODY ACHES/WEAKNESS
Dose per administration	1
Dose unit	mg ug mL g IU tablet capsule puff Other
If dose unit is Other, specify	APPLICATION
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)*	10 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ■ No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ☐

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Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Data signed: (b) (4) **15 Apr 2021 16:35:02**
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Name of Medication	FUROSEMIDE
Prophylaxis	Yes ☐ No ■
Indication	DIURETIC, FROM HOSPITALIZATION
Dose per administration	40
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ■ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ■ Transdermal ☐

	Intraocular ☐
	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	29 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	01 OCT 2020
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 ■

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Data signed: (b) (4) **15 Apr 2021 16:35:02**
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Name of Medication	METRONIDAZOLE
Prophylaxis	Yes No
Indication	UTI TREATMENT PART OF HOSPITALIZATION
Dose per administration	500
Dose unit	mg ug mL g IU tablet capsule puff Other
If dose unit is Other, specify	
Frequency	once daily twice daily three times daily four times daily every other day every week every month as needed once unknown other
If frequency is Other, specify	QGH
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)*	29 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	01 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 ☐

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Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Data signed: (b) (4) **15 Apr 2021 16:35:02**
Generated On: 09 Jun 2021 14:54:12

Name of Medication	MORPHINE SULFATE
Prophylaxis	Yes No ■
Indication	PAIN IN ABDOMEN PART OF HOSPITALIZATION (DIAGNOSED AS COLITIS)
Dose per administration	4
Dose unit	mg ■ ug mL g IU tablet capsule puff Other
If dose unit is Other, specify	
Frequency	once daily twice daily three times daily four times daily every other day every week every month as needed ■ once unknown other
If frequency is Other, specify	
Route of administration	Oral ■ Topical Subcutaneous Transdermal

	Intraocular ☐
	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	29 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	13 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 ☐

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Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Data signed: (b) (4) **15 Apr 2021 16:35:02**
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Name of Medication	METRONIDAZOLE
Prophylaxis	Yes ☐ No ■
Indication	UTI TREATMENT PRE-EMPTIVE PART OF HOSPITALIZATION
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	Q6H
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)*	29 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	01 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 ☐

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Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (30)
Data signed: (b) (4) **15 Apr 2021 16:35:02**
Generated On: 09 Jun 2021 14:54:12

Name of Medication	PANTOPRAZOLE SODIUM
Prophylaxis	Yes ☐ No ■
Indication	GERD DURING HOSPITALIZATION
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 ☐

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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)*	29 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	12 OCT 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 ■

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Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (31)
Data signed: (b) (4) **15 Apr 2021 16:35:02**
Generated On: 09 Jun 2021 14:54:12

Name of Medication	PANTOPRAZOLE SODIUM
Prophylaxis	Yes No
Indication	GERD DURING HOSPITALIZATION
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

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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)*	29 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	12 OCT 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 ■

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Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (32)
Data signed: (b) (4) **15 Apr 2021 16:35:02**
Generated On: 09 Jun 2021 14:54:12

Name of Medication	POLYETHYLENE GLYCOL
Prophylaxis	Yes ☐ No ■
Indication	PAIN IN ABDOMEN DX COLITIS
Dose per administration	17
Dose unit	mg ☐ ug ☐ mL ☐ g ■ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ■ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ 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)*	29 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	12 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 ☐

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Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (33)
Data signed: (b) (4) **15 Apr 2021 16:35:02**
Generated On: 09 Jun 2021 14:54:12

Name of Medication	TRAMADOL HCL
Prophylaxis	Yes ☐ No ■
Indication	PAIN IN ABDOMEN DX COLITIS DURING HOSPITALIZATION
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 ☐

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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)*	29 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	12 OCT 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 ■

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Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (34)
Data signed: (b) (4) **15 Apr 2021 16:35:02**
Generated On: 09 Jun 2021 14:54:12

Name of Medication	VILANTEROL/UMECLIDINIUM
Prophylaxis	Yes ☐ No ■
Indication	COPD- DURING HOSPITALIZATION
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 ☐

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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)*	29 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	12 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 ☐

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (35)
Data signed: (b) (4) **15 Apr 2021 16:35:02**
Generated On: 09 Jun 2021 14:54:12

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

	Intraocular ☐
	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	29 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	12 OCT 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 ■

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (36)
Data signed: (b) (4) **15 Apr 2021 16:35:02**
Generated On: 09 Jun 2021 14:54:12

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

	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)*	23 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	23 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 ☐

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (37)
Data signed: (b) (4) **15 Apr 2021 16:35:02**
Generated On: 09 Jun 2021 14:54:12

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

	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)*	27 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ■
If not Ongoing, End date *(dd MMM yyyy)*	27 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 ☐

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (38)
Data signed: (b) (4) **15 Apr 2021 16:35:02**
Generated On: 09 Jun 2021 14:54:12

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

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	03 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ■ No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (39)
Data signed: (b) (4) **15 Apr 2021 16:35:02**
Generated On: 09 Jun 2021 14:54:12

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

	Intramuscular ☐ Respiratory (Inhalation) ☐ Intralesional ☐ Intraperiteoneal ☐ Nasal ☐ Vaginal ☐ Rectal ☐ Intravenous ☐ Intravenous Bolus ☐ Intravenous Drip ☐ Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	13 OCT 2020
Start date completely unknown	False
Ongoing?	Yes ■ No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	
Interval Dosage Unit Number (derived)	
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ☐

US3012098
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Data signed: (b) (4) **05 Mar 2021 19:09:33**
Generated On: 09 Jun 2021 14:54:12

Were any concomitant procedures performed?	Yes ■ No ☐

If yes, please complete Concomitant Procedures form.

FDA-CBER-2022-1614-0004143

US3012098
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures
Data signed: (b) (4) **05 Mar 2021 19:09:33**
Generated On: 09 Jun 2021 14:54:12

Procedure/Surgery date *(dd MMM yyyy)*	Procedure/Surgery	Indication	If indication is Other, specify
29 SEP 2020	CHEST CT FOR PULMONARY EMBOLUS, NEGATIVE	Adverse Event	
14 OCT 2020	SARS-COV-2 TEST (NASAL, NEGATIVE)	Adverse Event	
29 SEP 2020	GI PANEL- BACTERIA PCR - NEGATIVE	Diagnostic	
30 SEP 2020	CHEST CT FOR PULMONARY EMBOLUS, NEGATIVE	Adverse Event	
29 SEP 2020	CT SCAN - ABDOMEN/PELVIS FOR DIAGNOSIS, NORMAL	Adverse Event	
30 SEP 2020	TRANSTHORACIC ECHOCARDIOGRAPH	Adverse Event	
29 SEP 2020	ELECTROCARDIOGRAM	Adverse Event	

US3012098
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Data signed: (b) (4) **05 Mar 2021 19:09:33**
Generated On: 09 Jun 2021 14:54:12

Date of study discontinuation/completion *(dd MMM yyyy)*	02 DEC 2020
Reason for discontinuation	AE (specify) ☐ SAE (specify) ☐ Complete ☐ Death ☐ Lost To Follow-up ☐ Physician decision (specify) ☐ Pregnancy ☐ Protocol deviation (specify) ☐ Study Terminated By Sponsor ☐ Withdrawal of consent by participant (specify) ■ Other ☐
If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify	SUBJECT WITHDREW FOR PERSONAL REASONS
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-2022-1614-0004145

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Data signed: (b) (4) **12 Mar 2021 19:15:26**
Generated On: 09 Jun 2021 14:54:12

SAEID	USA-US006-2020-MRNA-1273-P301000002
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	LAURENCE
Investigator's Last Name	CHU
Site Address: Street	3100 RED RIVER STREET
Site Address: City	AUSTIN
Site Address: State	TX
Site Address: Postal Code	78705
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	18

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form (1)
Data signed: (b) (4) **12 Mar 2021 19:15:26**
Generated On: 09 Jun 2021 14:54:12

SAEID	USA-US006-2020-MRNA-1273-P301000002
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	LAURENCE
Investigator's Last Name	CHU
Site Address: Street	3100 RED RIVER STREET
Site Address: City	AUSTIN
Site Address: State	TX
Site Address: Postal Code	78705
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	18
Date of submission (Pre-filled from custom function)	02/OCT/2020 12:35
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

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form (2)
Data signed: (b) (4) **12 Mar 2021 19:15:26**
Generated On: 09 Jun 2021 14:54:12

SAEID	USA-US006-2020-MRNA-1273-P301000002
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	LAURENCE
Investigator's Last Name	CHU
Site Address: Street	3100 RED RIVER STREET
Site Address: City	AUSTIN
Site Address: State	TX
Site Address: Postal Code	78705
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	18
Date of submission (Pre-filled from custom function)	12/OCT/2020 15:58
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form (3)
Data signed: (b) (4) **12 Mar 2021 19:15:26**
Generated On: 09 Jun 2021 14:54:12

SAEID	USA-US006-2020-MRNA-1273-P301000002
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	LAURENCE
Investigator's Last Name	CHU
Site Address: Street	3100 RED RIVER STREET
Site Address: City	AUSTIN
Site Address: State	TX
Site Address: Postal Code	78705
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	18
Date of submission (Pre-filled from custom function)	14/OCT/2020 13:51
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

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form (4)
Data signed: (b) (4) **12 Mar 2021 19:15:26**
Generated On: 09 Jun 2021 14:54:12

SAEID	USA-US006-2020-MRNA-1273-P301000002
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	LAURENCE
Investigator's Last Name	CHU
Site Address: Street	3100 RED RIVER STREET
Site Address: City	AUSTIN
Site Address: State	TX
Site Address: Postal Code	78705
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	18
Date of submission (Pre-filled from custom function)	21/OCT/2020 12:35
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

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form (5)
Data signed: (b) (4) **12 Mar 2021 19:15:26**
Generated On: 09 Jun 2021 14:54:12

SAEID	USA-US006-2020-MRNA-1273-P301000002
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	LAURENCE
Investigator's Last Name	CHU
Site Address: Street	3100 RED RIVER STREET
Site Address: City	AUSTIN
Site Address: State	TX
Site Address: Postal Code	78705
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	18
Date of submission (Pre-filled from custom function)	30/OCT/2020 09:58
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form (6)
Data signed: (b) (4) **12 Mar 2021 19:15:26**
Generated On: 09 Jun 2021 14:54:12

SAEID	USA-US006-2020-MRNA-1273-P301000002
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	LAURENCE
Investigator's Last Name	CHU
Site Address: Street	3100 RED RIVER STREET
Site Address: City	AUSTIN
Site Address: State	TX
Site Address: Postal Code	78705
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	18
Date of submission (Pre-filled from custom function)	02/NOV/2020 15:22
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

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form (7)
Data signed: (b) (4) **12 Mar 2021 19:15:26**
Generated On: 09 Jun 2021 14:54:12

SAEID	USA-US006-2020-MRNA-1273-P301000002
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	LAURENCE
Investigator's Last Name	CHU
Site Address: Street	3100 RED RIVER STREET
Site Address: City	AUSTIN
Site Address: State	TX
Site Address: Postal Code	78705
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	18
Date of submission (Pre-filled from custom function)	04/NOV/2020 09:12
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

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form (8)
Data signed: (b) (4) **12 Mar 2021 19:15:26**
Generated On: 09 Jun 2021 14:54:12

SAEID	USA-US006-2020-MRNA-1273-P301000002
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	LAURENCE
Investigator's Last Name	CHU
Site Address: Street	3100 RED RIVER STREET
Site Address: City	AUSTIN
Site Address: State	TX
Site Address: Postal Code	78705
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	18
Date of submission (Pre-filled from custom function)	06/NOV/2020 12:51
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

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form (9)
Data signed: (b) (4) **12 Mar 2021 19:15:26**
Generated On: 09 Jun 2021 14:54:12

SAEID	USA-US006-2020-MRNA-1273-P301000002
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	LAURENCE
Investigator's Last Name	CHU
Site Address: Street	3100 RED RIVER STREET
Site Address: City	AUSTIN
Site Address: State	TX
Site Address: Postal Code	78705
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	18
Date of submission (Pre-filled from custom function)	11/NOV/2020 16:58
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form (10)
Data signed: (b) (4) **12 Mar 2021 19:15:26**
Generated On: 09 Jun 2021 14:54:12

SAEID	USA-US006-2020-MRNA-1273-P301000002
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	LAURENCE
Investigator's Last Name	CHU
Site Address: Street	3100 RED RIVER STREET
Site Address: City	AUSTIN
Site Address: State	TX
Site Address: Postal Code	78705
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	18
Date of submission (Pre-filled from custom function)	19/NOV/2020 11:31
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

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form (11)
Data signed: (b) (4) **12 Mar 2021 19:15:26**
Generated On: 09 Jun 2021 14:54:12

SAEID	USA-US006-2020-MRNA-1273-P301000002
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	LAURENCE
Investigator's Last Name	CHU
Site Address: Street	3100 RED RIVER STREET
Site Address: City	AUSTIN
Site Address: State	TX
Site Address: Postal Code	78705
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	18
Date of submission (Pre-filled from custom function)	19/NOV/2020 12:47
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form (12)
Data signed: (b) (4) **12 Mar 2021 19:15:26**
Generated On: 09 Jun 2021 14:54:12

SAEID	USA-US006-2020-MRNA-1273-P301000002
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	LAURENCE
Investigator's Last Name	CHU
Site Address: Street	3100 RED RIVER STREET
Site Address: City	AUSTIN
Site Address: State	TX
Site Address: Postal Code	78705
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	18
Date of submission (Pre-filled from custom function)	25/NOV/2020 18:59
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

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form (13)
Data signed: (b) (4) **12 Mar 2021 19:15:26**
Generated On: 09 Jun 2021 14:54:12

SAEID	USA-US006-2020-MRNA-1273-P301000002
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	LAURENCE
Investigator's Last Name	CHU
Site Address: Street	3100 RED RIVER STREET
Site Address: City	AUSTIN
Site Address: State	TX
Site Address: Postal Code	78705
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	18
Date of submission (Pre-filled from custom function)	05/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

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form (14)
Data signed: (b) (4) **12 Mar 2021 19:15:26**
Generated On: 09 Jun 2021 14:54:12

SAEID	USA-US006-2020-MRNA-1273-P301000002
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	LAURENCE
Investigator's Last Name	CHU
Site Address: Street	3100 RED RIVER STREET
Site Address: City	AUSTIN
Site Address: State	TX
Site Address: Postal Code	78705
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	18
Date of submission (Pre-filled from custom function)	08/DEC/2020 09:58
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form (15)
Data signed: (b) (4) **12 Mar 2021 19:15:26**
Generated On: 09 Jun 2021 14:54:12

SAEID	USA-US006-2020-MRNA-1273-P301000002
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	LAURENCE
Investigator's Last Name	CHU
Site Address: Street	3100 RED RIVER STREET
Site Address: City	AUSTIN
Site Address: State	TX
Site Address: Postal Code	78705
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	18
Date of submission (Pre-filled from custom function)	10/DEC/2020 14:04
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

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form (16)
Data signed: (b) (4) **12 Mar 2021 19:15:26**
Generated On: 09 Jun 2021 14:54:12

SAEID	USA-US006-2020-MRNA-1273-P301000002
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	LAURENCE
Investigator's Last Name	CHU
Site Address: Street	3100 RED RIVER STREET
Site Address: City	AUSTIN
Site Address: State	TX
Site Address: Postal Code	78705
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	18
Date of submission (Pre-filled from custom function)	14/JAN/2021 11:31
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

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form (17)
Data signed: (b) (4) **12 Mar 2021 19:15:26**
Generated On: 09 Jun 2021 14:54:12

SAEID	USA-US006-2020-MRNA-1273-P301000002
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	LAURENCE
Investigator's Last Name	CHU
Site Address: Street	3100 RED RIVER STREET
Site Address: City	AUSTIN
Site Address: State	TX
Site Address: Postal Code	78705
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	18
Date of submission (Pre-filled from custom function)	04/MAR/2021 08:33
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

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form (18)
Data signed: (b) (4) **12 Mar 2021 19:15:26**
Generated On: 09 Jun 2021 14:54:12

SAEID	USA-US006-2020-MRNA-1273-P301000002
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	LAURENCE
Investigator's Last Name	CHU
Site Address: Street	3100 RED RIVER STREET
Site Address: City	AUSTIN
Site Address: State	TX
Site Address: Postal Code	78705
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	18
Date of submission (Pre-filled from custom function)	09/MAR/2021 08:58
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3012098 (Prod: Benchmark Research-Austin)

US3012098
Form: Participant Creation
Generated On: 09 Jun 2021 14:54:12
Participant ID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	16 Apr 2021 13:13:12
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'US3012098'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	10 Aug 2020 22:34:18

FDA-CBER-2022-1614-0004166

US3012098
Form: Participant Creation
Generated On: 09 Jun 2021 14:54:12

mRNA-1273-P301 Completion Guidelines

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09

FDA-CBER-2022-1614-0004167

US3012098
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 14:54:12
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	11 Aug 2020 00:32:47

FDA-CBER-2022-1614-0004168

US3012098
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 14:54:12
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '10 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	10 Aug 2020 22:34:19

FDA-CBER-2022-1614-0004169

US3012098
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 14:54:12
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Clinic (Clinic)'	Jennifer Leyva (b) (4) (b) (4)	11 Aug 2020 00:32:47

FDA-CBER-2022-1614-0004170

US3012098
Folder: Screening
Form: Visit Date
Generated On: 09 Jun 2021 14:54:12
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered 'SCRN'	(b) (4), (b) (6) System	11 Aug 2020 00:32:47

FDA-CBER-2022-1614-0004171

US3012098
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:54:12
Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '(b) (6)1959'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	10 Aug 2020 22:34:20

FDA-CBER-2022-1614-0004172

US3012098
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:54:12
Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '60'	Jennifer Leyva (b) (4) (b) (4)	11 Aug 2020 00:32:57

FDA-CBER-2022-1614-0004173

US3012098
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:54:12
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered 'YEARS'	System	11 Aug 2020 00:32:57

FDA-CBER-2022-1614-0004174

US3012098
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:54:12
Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '60'	System	11 Aug 2020 00:33:07

FDA-CBER-2022-1614-0004175

US3012098
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:54:12
Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Female (F)'	Jennifer Leyva (b) (4) (b) (4)	11 Aug 2020 00:32:57

FDA-CBER-2022-1614-0004176

US3012098
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:54:12
Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Jennifer Leyva (b) (4) (b) (4)	11 Aug 2020 00:32:57

FDA-CBER-2022-1614-0004177

US3012098
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:54:12
White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '1'	Jennifer Leyva (b) (4) (b) (4)	11 Aug 2020 00:32:57

FDA-CBER-2022-1614-0004178

US3012098
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:54:12
Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	11 Aug 2020 00:32:57

FDA-CBER-2022-1614-0004179

US3012098
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:54:12
Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	11 Aug 2020 00:32:57

FDA-CBER-2022-1614-0004180

US3012098
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:54:12
American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	11 Aug 2020 00:32:57

FDA-CBER-2022-1614-0004181

US3012098
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:54:12
Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	11 Aug 2020 00:32:57

FDA-CBER-2022-1614-0004182

US3012098
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:54:12
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	11 Aug 2020 00:32:57

FDA-CBER-2022-1614-0004183

US3012098
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:54:12
If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	11 Aug 2020 00:32:57

FDA-CBER-2022-1614-0004184

US3012098
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:54:12
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	11 Aug 2020 00:32:57

FDA-CBER-2022-1614-0004185

US3012098
Folder: Screening
Form: Demographics
Generated On: 09 Jun 2021 14:54:12
Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	11 Aug 2020 00:32:57

FDA-CBER-2022-1614-0004186

US3012098
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 14:54:12
Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '10 Aug 2020'	Jennifer Leyva (b) (4) (b) (4)	11 Aug 2020 00:33:07

FDA-CBER-2022-1614-0004187

US3012098
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 14:54:12
Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered 'Aug 2020'	(b) (4), (b) (6) System	11 Aug 2020 00:33:07

FDA-CBER-2022-1614-0004188

US3012098
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 14:54:12
Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '2020'	System	11 Aug 2020 00:33:07

FDA-CBER-2022-1614-0004189

US3012098
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 14:54:12
Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Amendment 2 (2)'	Jennifer Leyva (b) (4) (b) (4)	11 Aug 2020 00:33:07

FDA-CBER-2022-1614-0004190

US3012098
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 14:54:12
Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	11 Aug 2020 00:33:07

FDA-CBER-2022-1614-0004191

US3012098
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 14:54:12
If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	11 Aug 2020 00:33:07

FDA-CBER-2022-1614-0004192

US3012098
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 14:54:12
If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	11 Aug 2020 00:33:07

FDA-CBER-2022-1614-0004193

US3012098
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 14:54:12
Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	11 Aug 2020 00:33:07

US3012098
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 14:54:12
If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	10 Aug 2020 22:34:19

FDA-CBER-2022-1614-0004195

US3012098
Folder: Screening
Form: Enrollment
Generated On: 09 Jun 2021 14:54:12
Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '1'	System	11 Aug 2020 00:33:10

FDA-CBER-2022-1614-0004196

US3012098
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Generated On: 09 Jun 2021 14:54:12
Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	11 Aug 2020 00:33:10

US3012098
Folder: Screening
Form: Medical History Summary
Generated On: 09 Jun 2021 14:54:12
Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:08:30

FDA-CBER-2022-1614-0004198

US3012098
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 14:54:12
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 22:59:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 22:59:52
Data point term sent to Coder	System	11 Aug 2020 01:09:38
User entered 'lyrica allergy'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:08:51

US3012098
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 14:54:12
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'un UNK 1999'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:08:51

FDA-CBER-2022-1614-0004200

US3012098
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 14:54:12
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:08:51

FDA-CBER-2022-1614-0004201

US3012098
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 14:54:12
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:08:51

FDA-CBER-2022-1614-0004202

US3012098
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 14:54:12
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:08:51

US3012098
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 14:54:12
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:08:51

FDA-CBER-2022-1614-0004204

US3012098
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 14:54:12
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered 'Jan 1999'	System	11 Aug 2020 01:08:51

FDA-CBER-2022-1614-0004205

US3012098
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 14:54:12
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '1999'	System	11 Aug 2020 01:08:51

FDA-CBER-2022-1614-0004206

US3012098
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 14:54:12
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	11 Aug 2020 01:08:51

FDA-CBER-2022-1614-0004207

US3012098
Folder: Screening
Form: Medical History (1)
Generated On: 09 Jun 2021 14:54:12
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	11 Aug 2020 01:08:51

FDA-CBER-2022-1614-0004208

US3012098
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 14:54:12
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 22:39:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 22:39:58
Data point term sent to Coder	System	11 Aug 2020 01:09:38
User entered 'lithium allergy'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:09:11

US3012098
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 14:54:12
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'un UNK 1999'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:09:11

FDA-CBER-2022-1614-0004210

US3012098
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 14:54:12
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:09:11

FDA-CBER-2022-1614-0004211

US3012098
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 14:54:12
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:09:11

FDA-CBER-2022-1614-0004212

US3012098
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 14:54:12
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:09:11

FDA-CBER-2022-1614-0004213

US3012098
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 14:54:12
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:09:11

US3012098
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 14:54:12
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered 'Jan 1999'	System	11 Aug 2020 01:09:11

FDA-CBER-2022-1614-0004215

US3012098
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 14:54:12
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '1999'	(b) (4), (b) (6) System	11 Aug 2020 01:09:11

FDA-CBER-2022-1614-0004216

US3012098
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 14:54:12
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	11 Aug 2020 01:09:11

FDA-CBER-2022-1614-0004217

US3012098
Folder: Screening
Form: Medical History (2)
Generated On: 09 Jun 2021 14:54:12
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	11 Aug 2020 01:09:11

FDA-CBER-2022-1614-0004218

US3012098
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 14:54:12
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergy to antibiotic - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 17:09:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 17:09:24
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergy to antibiotic - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:10:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:10:19
Data point term sent to Coder	System	11 Aug 2020 01:09:38
User entered 'keflex allergy'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:09:31

US3012098
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 14:54:12
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'un UNK 1999'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:09:31

FDA-CBER-2022-1614-0004220

US3012098
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 14:54:12
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:09:31

FDA-CBER-2022-1614-0004221

US3012098
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 14:54:12
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:09:31

FDA-CBER-2022-1614-0004222

US3012098
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 14:54:12
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:09:31

US3012098
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 14:54:12
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:09:31

FDA-CBER-2022-1614-0004224

US3012098
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 14:54:12
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered 'Jan 1999'	System	11 Aug 2020 01:09:31

FDA-CBER-2022-1614-0004225

US3012098
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 14:54:12
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '1999'	System	11 Aug 2020 01:09:31

FDA-CBER-2022-1614-0004226

US3012098
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 14:54:12
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	11 Aug 2020 01:09:31

FDA-CBER-2022-1614-0004227

US3012098
Folder: Screening
Form: Medical History (3)
Generated On: 09 Jun 2021 14:54:12
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	11 Aug 2020 01:09:31

FDA-CBER-2022-1614-0004228

US3012098
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 14:54:12
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:12:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:12:22
Data point term sent to Coder	System	11 Aug 2020 01:10:38
User entered 'seasonal allergies'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:09:57

US3012098
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 14:54:12
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'un UNK 2000'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:09:57

FDA-CBER-2022-1614-0004230

US3012098
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 14:54:12
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:09:57

FDA-CBER-2022-1614-0004231

US3012098
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 14:54:12
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:09:57

FDA-CBER-2022-1614-0004232

US3012098
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 14:54:12
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:09:57

US3012098
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 14:54:12
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:09:57

FDA-CBER-2022-1614-0004234

US3012098
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 14:54:12
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered 'Jan 2000'	System	11 Aug 2020 01:09:57

FDA-CBER-2022-1614-0004235

US3012098
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 14:54:12
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '2000'	System	11 Aug 2020 01:09:57

FDA-CBER-2022-1614-0004236

US3012098
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 14:54:12
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	11 Aug 2020 01:09:57

FDA-CBER-2022-1614-0004237

US3012098
Folder: Screening
Form: Medical History (4)
Generated On: 09 Jun 2021 14:54:12
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	11 Aug 2020 01:09:57

FDA-CBER-2022-1614-0004238

US3012098
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 14:54:12
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: GERD - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:12:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:12:23
Data point term sent to Coder	System	11 Aug 2020 01:10:39
User entered 'GERD'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:10:32

US3012098
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 14:54:12
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'un UNK 2000'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:10:32

FDA-CBER-2022-1614-0004240

US3012098
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 14:54:12
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:10:32

FDA-CBER-2022-1614-0004241

US3012098
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 14:54:12
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:10:32

FDA-CBER-2022-1614-0004242

US3012098
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 14:54:12
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:10:32

US3012098
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 14:54:12
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:10:32

FDA-CBER-2022-1614-0004244

US3012098
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 14:54:12
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered 'Jan 2000'	System	11 Aug 2020 01:10:32

FDA-CBER-2022-1614-0004245

US3012098
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 14:54:12
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '2000'	System	11 Aug 2020 01:10:32

FDA-CBER-2022-1614-0004246

US3012098
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 14:54:12
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	11 Aug 2020 01:10:32

FDA-CBER-2022-1614-0004247

US3012098
Folder: Screening
Form: Medical History (5)
Generated On: 09 Jun 2021 14:54:12
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	11 Aug 2020 01:10:32

FDA-CBER-2022-1614-0004248

US3012098
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 14:54:12
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Dyspeptic signs and symptoms, PT: Dyspepsia, LLT: Heartburn - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:13:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:13:26
Data point term sent to Coder	System	11 Aug 2020 01:12:42
User entered 'heartburn'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:11:50

US3012098
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 14:54:12
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'un UNK 2000'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:11:50

FDA-CBER-2022-1614-0004250

US3012098
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 14:54:12
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:11:50

FDA-CBER-2022-1614-0004251

US3012098
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 14:54:12
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:11:50

FDA-CBER-2022-1614-0004252

US3012098
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 14:54:12
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:11:50

FDA-CBER-2022-1614-0004253

US3012098
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 14:54:12
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:11:50

FDA-CBER-2022-1614-0004254

US3012098
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 14:54:12
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered 'Jan 2000'	System	11 Aug 2020 01:11:50

FDA-CBER-2022-1614-0004255

US3012098
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 14:54:12
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '2000'	System	11 Aug 2020 01:11:50

FDA-CBER-2022-1614-0004256

US3012098
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 14:54:12
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	11 Aug 2020 01:11:50

FDA-CBER-2022-1614-0004257

US3012098
Folder: Screening
Form: Medical History (6)
Generated On: 09 Jun 2021 14:54:12
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	11 Aug 2020 01:11:50

FDA-CBER-2022-1614-0004258

US3012098
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 14:54:12
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Diverticulitis, LLT: Diverticulitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:13:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:13:26
Data point term sent to Coder	System	11 Aug 2020 01:12:40
User entered 'diverticulitis'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:12:21

US3012098
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 14:54:12
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'un UNK 2010'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:12:21

FDA-CBER-2022-1614-0004260

US3012098
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 14:54:12
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:12:21

FDA-CBER-2022-1614-0004261

US3012098
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 14:54:12
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:12:21

FDA-CBER-2022-1614-0004262

US3012098
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 14:54:12
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:12:21

FDA-CBER-2022-1614-0004263

US3012098
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 14:54:12
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:12:21

FDA-CBER-2022-1614-0004264

US3012098
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 14:54:12
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered 'Jan 2010'	System	11 Aug 2020 01:12:21

FDA-CBER-2022-1614-0004265

US3012098
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 14:54:12
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '2010'	System	11 Aug 2020 01:12:21

FDA-CBER-2022-1614-0004266

US3012098
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 14:54:12
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	11 Aug 2020 01:12:21

FDA-CBER-2022-1614-0004267

US3012098
Folder: Screening
Form: Medical History (7)
Generated On: 09 Jun 2021 14:54:12
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	11 Aug 2020 01:12:21

FDA-CBER-2022-1614-0004268

US3012098
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 14:54:12
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:14:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:14:28
Data point term sent to Coder	System	11 Aug 2020 01:13:42
User entered 'obesity'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:12:50

US3012098
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 14:54:12
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'un UNK 1980'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:12:50

FDA-CBER-2022-1614-0004270

US3012098
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 14:54:12
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:12:50

US3012098
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 14:54:12
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:12:50

FDA-CBER-2022-1614-0004272

US3012098
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 14:54:12
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:12:50

FDA-CBER-2022-1614-0004273

US3012098
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 14:54:12
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:12:50

FDA-CBER-2022-1614-0004274

US3012098
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 14:54:12
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered 'Jan 1980'	System	11 Aug 2020 01:12:50

FDA-CBER-2022-1614-0004275

US3012098
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 14:54:12
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '1980'	System	11 Aug 2020 01:12:50

FDA-CBER-2022-1614-0004276

US3012098
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 14:54:12
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	11 Aug 2020 01:12:50

FDA-CBER-2022-1614-0004277

US3012098
Folder: Screening
Form: Medical History (8)
Generated On: 09 Jun 2021 14:54:12
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	(b) (4), (b) (6) System	11 Aug 2020 01:12:50

FDA-CBER-2022-1614-0004278

US3012098
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 14:54:12
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:14:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:14:29
Data point term sent to Coder	System	11 Aug 2020 01:13:42
User entered 'hypothyroidism'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:13:14

FDA-CBER-2022-1614-0004279

US3012098
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 14:54:12
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'un UNK 1990'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:13:14

FDA-CBER-2022-1614-0004280

US3012098
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 14:54:12
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:13:14

FDA-CBER-2022-1614-0004281

US3012098
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 14:54:12
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:13:14

FDA-CBER-2022-1614-0004282

US3012098
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 14:54:12
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:13:14

FDA-CBER-2022-1614-0004283

US3012098
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 14:54:12
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:13:14

FDA-CBER-2022-1614-0004284

US3012098
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 14:54:12
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered 'Jan 1990'	System	11 Aug 2020 01:13:14

FDA-CBER-2022-1614-0004285

US3012098
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 14:54:12
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '1990'	System	11 Aug 2020 01:13:14

FDA-CBER-2022-1614-0004286

US3012098
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 14:54:12
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	11 Aug 2020 01:13:14

FDA-CBER-2022-1614-0004287

US3012098
Folder: Screening
Form: Medical History (9)
Generated On: 09 Jun 2021 14:54:12
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	11 Aug 2020 01:13:14

FDA-CBER-2022-1614-0004288

US3012098
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 14:54:12
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Menopause, LLT: Menopause - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:14:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:14:28
Data point term sent to Coder	System	11 Aug 2020 01:13:42
User entered 'menopause'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:13:36

FDA-CBER-2022-1614-0004289

US3012098
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 14:54:12
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'un UNK 2005'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:13:36

FDA-CBER-2022-1614-0004290

US3012098
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 14:54:12
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:13:36

FDA-CBER-2022-1614-0004291

US3012098
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 14:54:12
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:13:36

FDA-CBER-2022-1614-0004292

US3012098
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 14:54:12
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:13:36

FDA-CBER-2022-1614-0004293

US3012098
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 14:54:12
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:13:36

FDA-CBER-2022-1614-0004294

US3012098
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 14:54:12
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered 'Jan 2005'	System	11 Aug 2020 01:13:36

FDA-CBER-2022-1614-0004295

US3012098
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 14:54:12
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '2005'	System	11 Aug 2020 01:13:36

FDA-CBER-2022-1614-0004296

US3012098
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 14:54:12
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	11 Aug 2020 01:13:36

FDA-CBER-2022-1614-0004297

US3012098
Folder: Screening
Form: Medical History (10)
Generated On: 09 Jun 2021 14:54:12
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	11 Aug 2020 01:13:36

FDA-CBER-2022-1614-0004298

US3012098
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 14:54:12
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User coded data point as SOC: Renal and urinary disorders, HLGT: Bladder and bladder neck disorders (excl calculi), HLT: Myoneurogenic bladder disorders, PT: Hypertonic bladder, LLT: Overactive bladder - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:15:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:15:17
Data point term sent to Coder	System	11 Aug 2020 01:14:43
User entered 'overactive bladder'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:14:22

US3012098
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 14:54:12
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'un UNK 2005'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:14:22

FDA-CBER-2022-1614-0004300

US3012098
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 14:54:12
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:14:22

FDA-CBER-2022-1614-0004301

US3012098
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 14:54:12
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:14:22

FDA-CBER-2022-1614-0004302

US3012098
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 14:54:12
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:14:22

FDA-CBER-2022-1614-0004303

US3012098
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 14:54:12
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:14:22

FDA-CBER-2022-1614-0004304

US3012098
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 14:54:12
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered 'Jan 2005'	System	11 Aug 2020 01:14:22

FDA-CBER-2022-1614-0004305

US3012098
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 14:54:12
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '2005'	System	11 Aug 2020 01:14:22

FDA-CBER-2022-1614-0004306

US3012098
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 14:54:12
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	11 Aug 2020 01:14:22

FDA-CBER-2022-1614-0004307

US3012098
Folder: Screening
Form: Medical History (11)
Generated On: 09 Jun 2021 14:54:12
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	11 Aug 2020 01:14:22

FDA-CBER-2022-1614-0004308

US3012098
Folder: Screening
Form: Medical History (12)
Generated On: 09 Jun 2021 14:54:12
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
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)	11 Aug 2020 01:16:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:16:24
Data point term sent to Coder	System	11 Aug 2020 01:15:43
User entered 'hypertension'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:14:52

US3012098
Folder: Screening
Form: Medical History (12)
Generated On: 09 Jun 2021 14:54:12
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'un UNK 2019'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:14:52

FDA-CBER-2022-1614-0004310

US3012098
Folder: Screening
Form: Medical History (12)
Generated On: 09 Jun 2021 14:54:12
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:14:52

FDA-CBER-2022-1614-0004311

US3012098
Folder: Screening
Form: Medical History (12)
Generated On: 09 Jun 2021 14:54:12
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:14:52

FDA-CBER-2022-1614-0004312

US3012098
Folder: Screening
Form: Medical History (12)
Generated On: 09 Jun 2021 14:54:12
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:14:52

FDA-CBER-2022-1614-0004313

US3012098
Folder: Screening
Form: Medical History (12)
Generated On: 09 Jun 2021 14:54:12
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:14:52

FDA-CBER-2022-1614-0004314

US3012098
Folder: Screening
Form: Medical History (12)
Generated On: 09 Jun 2021 14:54:12
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered 'Jan 2019'	System	11 Aug 2020 01:14:52

FDA-CBER-2022-1614-0004315

US3012098
Folder: Screening
Form: Medical History (12)
Generated On: 09 Jun 2021 14:54:12
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '2019'	System	11 Aug 2020 01:14:52

FDA-CBER-2022-1614-0004316

US3012098
Folder: Screening
Form: Medical History (12)
Generated On: 09 Jun 2021 14:54:12
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	11 Aug 2020 01:14:52

FDA-CBER-2022-1614-0004317

US3012098
Folder: Screening
Form: Medical History (12)
Generated On: 09 Jun 2021 14:54:12
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	11 Aug 2020 01:14:52

FDA-CBER-2022-1614-0004318

US3012098
Folder: Screening
Form: Medical History (13)
Generated On: 09 Jun 2021 14:54:12
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
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)	11 Aug 2020 01:16:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:16:24
Data point term sent to Coder	System	11 Aug 2020 01:15:43
User entered 'hypercholesterolemia'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:15:15

US3012098
Folder: Screening
Form: Medical History (13)
Generated On: 09 Jun 2021 14:54:12
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'un UNK 2019'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:15:15

FDA-CBER-2022-1614-0004320

US3012098
Folder: Screening
Form: Medical History (13)
Generated On: 09 Jun 2021 14:54:12
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:15:15

FDA-CBER-2022-1614-0004321

US3012098
Folder: Screening
Form: Medical History (13)
Generated On: 09 Jun 2021 14:54:12
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:15:15

FDA-CBER-2022-1614-0004322

US3012098
Folder: Screening
Form: Medical History (13)
Generated On: 09 Jun 2021 14:54:12
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:15:15

FDA-CBER-2022-1614-0004323

US3012098
Folder: Screening
Form: Medical History (13)
Generated On: 09 Jun 2021 14:54:12
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:15:15

FDA-CBER-2022-1614-0004324

US3012098
Folder: Screening
Form: Medical History (13)
Generated On: 09 Jun 2021 14:54:12
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered 'Jan 2019'	System	11 Aug 2020 01:15:15

FDA-CBER-2022-1614-0004325

US3012098
Folder: Screening
Form: Medical History (13)
Generated On: 09 Jun 2021 14:54:12
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '2019'	(b) (4), (b) (6) System	11 Aug 2020 01:15:15

FDA-CBER-2022-1614-0004326

US3012098
Folder: Screening
Form: Medical History (13)
Generated On: 09 Jun 2021 14:54:12
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	11 Aug 2020 01:15:15

FDA-CBER-2022-1614-0004327

US3012098
Folder: Screening
Form: Medical History (13)
Generated On: 09 Jun 2021 14:54:12
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	11 Aug 2020 01:15:15

FDA-CBER-2022-1614-0004328

US3012098
Folder: Screening
Form: Medical History (14)
Generated On: 09 Jun 2021 14:54:12
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Lower respiratory tract disorders (excl obstruction and infection), HLT: Parenchymal lung disorders NEC, PT: Emphysema, LLT: Emphysema - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:17:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:17:25
Data point term sent to Coder	System	11 Aug 2020 01:16:44
User entered 'emphysema'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:15:48

US3012098
Folder: Screening
Form: Medical History (14)
Generated On: 09 Jun 2021 14:54:12
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'un UNK 2019'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:15:48

FDA-CBER-2022-1614-0004330

US3012098
Folder: Screening
Form: Medical History (14)
Generated On: 09 Jun 2021 14:54:12
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:15:48

FDA-CBER-2022-1614-0004331

US3012098
Folder: Screening
Form: Medical History (14)
Generated On: 09 Jun 2021 14:54:12
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:15:48

FDA-CBER-2022-1614-0004332

US3012098
Folder: Screening
Form: Medical History (14)
Generated On: 09 Jun 2021 14:54:12
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:15:48

FDA-CBER-2022-1614-0004333

US3012098
Folder: Screening
Form: Medical History (14)
Generated On: 09 Jun 2021 14:54:12
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:15:48

FDA-CBER-2022-1614-0004334

US3012098
Folder: Screening
Form: Medical History (14)
Generated On: 09 Jun 2021 14:54:12
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered 'Jan 2019'	System	11 Aug 2020 01:15:48

FDA-CBER-2022-1614-0004335

US3012098
Folder: Screening
Form: Medical History (14)
Generated On: 09 Jun 2021 14:54:12
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '2019'	System	11 Aug 2020 01:15:48

FDA-CBER-2022-1614-0004336

US3012098
Folder: Screening
Form: Medical History (14)
Generated On: 09 Jun 2021 14:54:12
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	11 Aug 2020 01:15:48

FDA-CBER-2022-1614-0004337

US3012098
Folder: Screening
Form: Medical History (14)
Generated On: 09 Jun 2021 14:54:12
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	11 Aug 2020 01:15:48

FDA-CBER-2022-1614-0004338

US3012098
Folder: Screening
Form: Medical History (15)
Generated On: 09 Jun 2021 14:54:12
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:18:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:18:11
Data point term sent to Coder	System	11 Aug 2020 01:16:44
User entered 'depression'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:16:19

FDA-CBER-2022-1614-0004339

US3012098
Folder: Screening
Form: Medical History (15)
Generated On: 09 Jun 2021 14:54:12
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'un UNK 2000'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:16:19

FDA-CBER-2022-1614-0004340

US3012098
Folder: Screening
Form: Medical History (15)
Generated On: 09 Jun 2021 14:54:12
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:16:19

FDA-CBER-2022-1614-0004341

US3012098
Folder: Screening
Form: Medical History (15)
Generated On: 09 Jun 2021 14:54:12
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:16:19

FDA-CBER-2022-1614-0004342

US3012098
Folder: Screening
Form: Medical History (15)
Generated On: 09 Jun 2021 14:54:12
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:16:19

FDA-CBER-2022-1614-0004343

US3012098
Folder: Screening
Form: Medical History (15)
Generated On: 09 Jun 2021 14:54:12
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:16:19

FDA-CBER-2022-1614-0004344

US3012098
Folder: Screening
Form: Medical History (15)
Generated On: 09 Jun 2021 14:54:12
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered 'Jan 2000'	System	11 Aug 2020 01:16:19

FDA-CBER-2022-1614-0004345

US3012098
Folder: Screening
Form: Medical History (15)
Generated On: 09 Jun 2021 14:54:12
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '2000'	System	11 Aug 2020 01:16:19

FDA-CBER-2022-1614-0004346

US3012098
Folder: Screening
Form: Medical History (15)
Generated On: 09 Jun 2021 14:54:12
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	11 Aug 2020 01:16:19

FDA-CBER-2022-1614-0004347

US3012098
Folder: Screening
Form: Medical History (15)
Generated On: 09 Jun 2021 14:54:12
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	11 Aug 2020 01:16:19

FDA-CBER-2022-1614-0004348

US3012098
Folder: Screening
Form: Medical History (16)
Generated On: 09 Jun 2021 14:54:12
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:18:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:18:26
Data point term sent to Coder	System	11 Aug 2020 01:17:44
User entered 'anxiety'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:16:44

FDA-CBER-2022-1614-0004349

US3012098
Folder: Screening
Form: Medical History (16)
Generated On: 09 Jun 2021 14:54:12
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'un UNK 2000'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:16:44

FDA-CBER-2022-1614-0004350

US3012098
Folder: Screening
Form: Medical History (16)
Generated On: 09 Jun 2021 14:54:12
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:16:44

FDA-CBER-2022-1614-0004351

US3012098
Folder: Screening
Form: Medical History (16)
Generated On: 09 Jun 2021 14:54:12
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:16:44

FDA-CBER-2022-1614-0004352

US3012098
Folder: Screening
Form: Medical History (16)
Generated On: 09 Jun 2021 14:54:12
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:16:44

FDA-CBER-2022-1614-0004353

US3012098
Folder: Screening
Form: Medical History (16)
Generated On: 09 Jun 2021 14:54:12
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:16:44

FDA-CBER-2022-1614-0004354

US3012098
Folder: Screening
Form: Medical History (16)
Generated On: 09 Jun 2021 14:54:12
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered 'Jan 2000'	System	11 Aug 2020 01:16:44

FDA-CBER-2022-1614-0004355

US3012098
Folder: Screening
Form: Medical History (16)
Generated On: 09 Jun 2021 14:54:12
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '2000'	System	11 Aug 2020 01:16:44

FDA-CBER-2022-1614-0004356

US3012098
Folder: Screening
Form: Medical History (16)
Generated On: 09 Jun 2021 14:54:12
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	11 Aug 2020 01:16:44

FDA-CBER-2022-1614-0004357

US3012098
Folder: Screening
Form: Medical History (16)
Generated On: 09 Jun 2021 14:54:12
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	11 Aug 2020 01:16:44

FDA-CBER-2022-1614-0004358

US3012098
Folder: Screening
Form: Medical History (17)
Generated On: 09 Jun 2021 14:54:12
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Panic attacks and disorders, PT: Panic attack, LLT: Panic attacks - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:18:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:18:26
Data point term sent to Coder	System	11 Aug 2020 01:17:44
User entered 'panic attacks'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:17:06

US3012098
Folder: Screening
Form: Medical History (17)
Generated On: 09 Jun 2021 14:54:12
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'un UNK 2000'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:17:06

FDA-CBER-2022-1614-0004360

US3012098
Folder: Screening
Form: Medical History (17)
Generated On: 09 Jun 2021 14:54:12
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:17:06

FDA-CBER-2022-1614-0004361

US3012098
Folder: Screening
Form: Medical History (17)
Generated On: 09 Jun 2021 14:54:12
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:17:06

FDA-CBER-2022-1614-0004362

US3012098
Folder: Screening
Form: Medical History (17)
Generated On: 09 Jun 2021 14:54:12
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:17:06

FDA-CBER-2022-1614-0004363

US3012098
Folder: Screening
Form: Medical History (17)
Generated On: 09 Jun 2021 14:54:12
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:17:06

FDA-CBER-2022-1614-0004364

US3012098
Folder: Screening
Form: Medical History (17)
Generated On: 09 Jun 2021 14:54:12
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered 'Jan 2000'	System	11 Aug 2020 01:17:06

FDA-CBER-2022-1614-0004365

US3012098
Folder: Screening
Form: Medical History (17)
Generated On: 09 Jun 2021 14:54:12
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '2000'	System	11 Aug 2020 01:17:06

FDA-CBER-2022-1614-0004366

US3012098
Folder: Screening
Form: Medical History (17)
Generated On: 09 Jun 2021 14:54:12
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	11 Aug 2020 01:17:06

FDA-CBER-2022-1614-0004367

US3012098
Folder: Screening
Form: Medical History (17)
Generated On: 09 Jun 2021 14:54:12
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	11 Aug 2020 01:17:06

FDA-CBER-2022-1614-0004368

US3012098
Folder: Screening
Form: Medical History (18)
Generated On: 09 Jun 2021 14:54:12
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User coded data point as SOC: Psychiatric disorders, HLGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:18:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:18:26
Data point term sent to Coder	System	11 Aug 2020 01:17:45
User entered 'insomnia'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:17:37

FDA-CBER-2022-1614-0004369

US3012098
Folder: Screening
Form: Medical History (18)
Generated On: 09 Jun 2021 14:54:12
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'un UNK 2000'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:17:37

FDA-CBER-2022-1614-0004370

US3012098
Folder: Screening
Form: Medical History (18)
Generated On: 09 Jun 2021 14:54:12
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:17:37

FDA-CBER-2022-1614-0004371

US3012098
Folder: Screening
Form: Medical History (18)
Generated On: 09 Jun 2021 14:54:12
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:17:37

FDA-CBER-2022-1614-0004372

US3012098
Folder: Screening
Form: Medical History (18)
Generated On: 09 Jun 2021 14:54:12
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:17:37

FDA-CBER-2022-1614-0004373

US3012098
Folder: Screening
Form: Medical History (18)
Generated On: 09 Jun 2021 14:54:12
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:17:37

FDA-CBER-2022-1614-0004374

US3012098
Folder: Screening
Form: Medical History (18)
Generated On: 09 Jun 2021 14:54:12
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered 'Jan 2000'	System	11 Aug 2020 01:17:37

FDA-CBER-2022-1614-0004375

US3012098
Folder: Screening
Form: Medical History (18)
Generated On: 09 Jun 2021 14:54:12
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '2000'	System	11 Aug 2020 01:17:37

FDA-CBER-2022-1614-0004376

US3012098
Folder: Screening
Form: Medical History (18)
Generated On: 09 Jun 2021 14:54:12
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	11 Aug 2020 01:17:37

FDA-CBER-2022-1614-0004377

US3012098
Folder: Screening
Form: Medical History (18)
Generated On: 09 Jun 2021 14:54:12
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	11 Aug 2020 01:17:37

FDA-CBER-2022-1614-0004378

US3012098
Folder: Screening
Form: Medical History (19)
Generated On: 09 Jun 2021 14:54:12
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
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)	14 Aug 2020 10:36:12
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Aug 2020 10:36:12
Data point term sent to Coder	System	11 Aug 2020 01:18:47
User entered 'osteoarthritis (lower back, lower neck)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:18:23

FDA-CBER-2022-1614-0004379

US3012098
Folder: Screening
Form: Medical History (19)
Generated On: 09 Jun 2021 14:54:12
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'un UNK 2010'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:18:23

FDA-CBER-2022-1614-0004380

US3012098
Folder: Screening
Form: Medical History (19)
Generated On: 09 Jun 2021 14:54:12
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:18:23

FDA-CBER-2022-1614-0004381

US3012098
Folder: Screening
Form: Medical History (19)
Generated On: 09 Jun 2021 14:54:12
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:18:23

FDA-CBER-2022-1614-0004382

US3012098
Folder: Screening
Form: Medical History (19)
Generated On: 09 Jun 2021 14:54:12
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:18:23

FDA-CBER-2022-1614-0004383

US3012098
Folder: Screening
Form: Medical History (19)
Generated On: 09 Jun 2021 14:54:12
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:18:23

FDA-CBER-2022-1614-0004384

US3012098
Folder: Screening
Form: Medical History (19)
Generated On: 09 Jun 2021 14:54:12
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered 'Jan 2010'	System	11 Aug 2020 01:18:23

FDA-CBER-2022-1614-0004385

US3012098
Folder: Screening
Form: Medical History (19)
Generated On: 09 Jun 2021 14:54:12
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '2010'	System	11 Aug 2020 01:18:23

FDA-CBER-2022-1614-0004386

US3012098
Folder: Screening
Form: Medical History (19)
Generated On: 09 Jun 2021 14:54:12
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	11 Aug 2020 01:18:23

FDA-CBER-2022-1614-0004387

US3012098
Folder: Screening
Form: Medical History (19)
Generated On: 09 Jun 2021 14:54:12
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	11 Aug 2020 01:18:23

FDA-CBER-2022-1614-0004388

US3012098
Folder: Screening
Form: Medical History (20)
Generated On: 09 Jun 2021 14:54:12
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Lumbar pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 06:42:23
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 06:42:23
Data point term sent to Coder	System	11 Aug 2020 01:19:50
User entered 'BACK PAIN LUMBaR REGION' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:18:59
User entered 'back pain lumber region'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:18:52

FDA-CBER-2022-1614-0004389

US3012098
Folder: Screening
Form: Medical History (20)
Generated On: 09 Jun 2021 14:54:12
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'un UNK 2000'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:18:52

FDA-CBER-2022-1614-0004390

US3012098
Folder: Screening
Form: Medical History (20)
Generated On: 09 Jun 2021 14:54:12
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:18:52

FDA-CBER-2022-1614-0004391

US3012098
Folder: Screening
Form: Medical History (20)
Generated On: 09 Jun 2021 14:54:12
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:18:52

FDA-CBER-2022-1614-0004392

US3012098
Folder: Screening
Form: Medical History (20)
Generated On: 09 Jun 2021 14:54:12
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:18:52

FDA-CBER-2022-1614-0004393

US3012098
Folder: Screening
Form: Medical History (20)
Generated On: 09 Jun 2021 14:54:12
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:18:52

FDA-CBER-2022-1614-0004394

US3012098
Folder: Screening
Form: Medical History (20)
Generated On: 09 Jun 2021 14:54:12
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered 'Jan 2000'	System	11 Aug 2020 01:18:52

FDA-CBER-2022-1614-0004395

US3012098
Folder: Screening
Form: Medical History (20)
Generated On: 09 Jun 2021 14:54:12
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '2000'	System	11 Aug 2020 01:18:52

FDA-CBER-2022-1614-0004396

US3012098
Folder: Screening
Form: Medical History (20)
Generated On: 09 Jun 2021 14:54:12
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	11 Aug 2020 01:18:52

FDA-CBER-2022-1614-0004397

US3012098
Folder: Screening
Form: Medical History (20)
Generated On: 09 Jun 2021 14:54:12
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	11 Aug 2020 01:18:52

FDA-CBER-2022-1614-0004398

US3012098
Folder: Screening
Form: Medical History (21)
Generated On: 09 Jun 2021 14:54:12
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Fibromyalgia, LLT: Fibromyalgia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:20:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:20:27
Data point term sent to Coder	System	11 Aug 2020 01:19:50
User entered 'fibromyalgia'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:19:28

US3012098
Folder: Screening
Form: Medical History (21)
Generated On: 09 Jun 2021 14:54:12
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'un UNK 2000'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:19:28

FDA-CBER-2022-1614-0004400

US3012098
Folder: Screening
Form: Medical History (21)
Generated On: 09 Jun 2021 14:54:12
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:19:28

FDA-CBER-2022-1614-0004401

US3012098
Folder: Screening
Form: Medical History (21)
Generated On: 09 Jun 2021 14:54:12
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:19:28

FDA-CBER-2022-1614-0004402

US3012098
Folder: Screening
Form: Medical History (21)
Generated On: 09 Jun 2021 14:54:12
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:19:28

FDA-CBER-2022-1614-0004403

US3012098
Folder: Screening
Form: Medical History (21)
Generated On: 09 Jun 2021 14:54:12
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:19:28

FDA-CBER-2022-1614-0004404

US3012098
Folder: Screening
Form: Medical History (21)
Generated On: 09 Jun 2021 14:54:12
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered 'Jan 2000'	System	11 Aug 2020 01:19:28

FDA-CBER-2022-1614-0004405

US3012098
Folder: Screening
Form: Medical History (21)
Generated On: 09 Jun 2021 14:54:12
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '2000'	System	11 Aug 2020 01:19:28

FDA-CBER-2022-1614-0004406

US3012098
Folder: Screening
Form: Medical History (21)
Generated On: 09 Jun 2021 14:54:12
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	11 Aug 2020 01:19:28

FDA-CBER-2022-1614-0004407

US3012098
Folder: Screening
Form: Medical History (21)
Generated On: 09 Jun 2021 14:54:12
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	11 Aug 2020 01:19:28

FDA-CBER-2022-1614-0004408

US3012098
Folder: Screening
Form: Medical History (22)
Generated On: 09 Jun 2021 14:54:12
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Umbilical hernias, PT: Umbilical hernia, LLT: Umbilical hernia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:21:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:21:16
Data point term sent to Coder	System	11 Aug 2020 01:20:51
User entered 'umbilical hernia'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:20:19

US3012098
Folder: Screening
Form: Medical History (22)
Generated On: 09 Jun 2021 14:54:12
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'un UNK 1997'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:20:19

FDA-CBER-2022-1614-0004410

US3012098
Folder: Screening
Form: Medical History (22)
Generated On: 09 Jun 2021 14:54:12
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:20:19

FDA-CBER-2022-1614-0004411

US3012098
Folder: Screening
Form: Medical History (22)
Generated On: 09 Jun 2021 14:54:12
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:20:19

US3012098
Folder: Screening
Form: Medical History (22)
Generated On: 09 Jun 2021 14:54:12
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:20:19

FDA-CBER-2022-1614-0004413

US3012098
Folder: Screening
Form: Medical History (22)
Generated On: 09 Jun 2021 14:54:12
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:20:19

FDA-CBER-2022-1614-0004414

US3012098
Folder: Screening
Form: Medical History (22)
Generated On: 09 Jun 2021 14:54:12
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered 'Jan 1997'	System	11 Aug 2020 01:20:19

FDA-CBER-2022-1614-0004415

US3012098
Folder: Screening
Form: Medical History (22)
Generated On: 09 Jun 2021 14:54:12
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '1997'	System	11 Aug 2020 01:20:19

FDA-CBER-2022-1614-0004416

US3012098
Folder: Screening
Form: Medical History (22)
Generated On: 09 Jun 2021 14:54:12
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	11 Aug 2020 01:20:19

FDA-CBER-2022-1614-0004417

US3012098
Folder: Screening
Form: Medical History (22)
Generated On: 09 Jun 2021 14:54:12
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	11 Aug 2020 01:20:19

FDA-CBER-2022-1614-0004418

US3012098
Folder: Screening
Form: Medical History (23)
Generated On: 09 Jun 2021 14:54:12
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User coded data point as SOC: Psychiatric disorders, HLGT: Manic and bipolar mood disorders and disturbances, HLT: Bipolar disorders, PT: Bipolar disorder, LLT: Bipolar disorder - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 01:23:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 01:23:53
Data point term sent to Coder	System	03 Oct 2020 01:23:09
User entered 'BIPOLAR DISORDER'	Lamar Box (b) (4) (b) (4)	03 Oct 2020 01:22:31

FDA-CBER-2022-1614-0004419

US3012098
Folder: Screening
Form: Medical History (23)
Generated On: 09 Jun 2021 14:54:12
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'UN UNK 2000'	Lamar Box (b) (4) (b) (4)	03 Oct 2020 01:22:31

FDA-CBER-2022-1614-0004420

US3012098
Folder: Screening
Form: Medical History (23)
Generated On: 09 Jun 2021 14:54:12
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	Lamar Box (b) (4) (b) (4)	03 Oct 2020 01:22:31

FDA-CBER-2022-1614-0004421

US3012098
Folder: Screening
Form: Medical History (23)
Generated On: 09 Jun 2021 14:54:12
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	Lamar Box (b) (4) (b) (4)	03 Oct 2020 01:22:31

FDA-CBER-2022-1614-0004422

US3012098
Folder: Screening
Form: Medical History (23)
Generated On: 09 Jun 2021 14:54:12
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	Lamar Box (b) (4) (b) (4)	03 Oct 2020 01:22:31

FDA-CBER-2022-1614-0004423

US3012098
Folder: Screening
Form: Medical History (23)
Generated On: 09 Jun 2021 14:54:12
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	Lamar Box (b) (4) (b) (4)	03 Oct 2020 01:22:31

FDA-CBER-2022-1614-0004424

US3012098
Folder: Screening
Form: Medical History (23)
Generated On: 09 Jun 2021 14:54:12
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered 'Jan 2000'	System	03 Oct 2020 01:22:31

FDA-CBER-2022-1614-0004425

US3012098
Folder: Screening
Form: Medical History (23)
Generated On: 09 Jun 2021 14:54:12
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '2000'	System	03 Oct 2020 01:22:31

FDA-CBER-2022-1614-0004426

US3012098
Folder: Screening
Form: Medical History (23)
Generated On: 09 Jun 2021 14:54:12
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	03 Oct 2020 01:22:31

FDA-CBER-2022-1614-0004427

US3012098
Folder: Screening
Form: Medical History (23)
Generated On: 09 Jun 2021 14:54:12
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	03 Oct 2020 01:22:31

FDA-CBER-2022-1614-0004428

US3012098
Folder: Screening
Form: Medical History (24)
Generated On: 09 Jun 2021 14:54:12
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User closed query 'Per DM CLR: Please review if this MH and MH #14 EMPHYSEMA (UN UNK 2019-Ongoing) are related, as they have overlapping timeframe. If related, please combine as one MH indicating the underlying condition/diagnosis. Update eCRF as appropriate, or provide clarification. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 04:24:09
Query 'Per DM CLR: Please review if this MH and MH #14 EMPHYSEMA (UN UNK 2019-Ongoing) are related, as they have overlapping timeframe. If related, please combine as one MH indicating the underlying condition/diagnosis. Update eCRF as appropriate, or provide clarification. ' answered with 'COPD and Emphysema are two separate conditions.' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	23 Oct 2020 16:09:03
User opened query 'Per DM CLR: Please review if this MH and MH #14 EMPHYSEMA (UN UNK 2019-Ongoing) are related, as they have overlapping timeframe. If related, please combine as one MH indicating the underlying condition/diagnosis. Update eCRF as appropriate, or provide clarification. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	22 Oct 2020 08:42:02
Query 'Per DM CLR: Please review if this MH and MH #14 EMPHYSEMA (UN UNK 2019-Ongoing) are related, as they have overlapping timeframe. If related, please combine as one MH indicating the underlying condition/diagnosis instead of separate symptoms. Update eCRF as appropriate, or provide clarification. ' canceled (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	22 Oct 2020 08:41:35
User opened query 'Per DM CLR: Please review if this MH and MH #14 EMPHYSEMA (UN UNK 2019-Ongoing) are related, as they have overlapping timeframe. If related, please combine as one MH indicating the underlying condition/diagnosis instead of separate symptoms. Update eCRF as appropriate, or provide clarification. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	22 Oct 2020 08:41:27

US3012098
Folder: Screening
Form: Medical History (24)
Generated On: 09 Jun 2021 14:54:12
Condition

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: COPD - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 19:18:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 19:18:45
Data point term sent to Coder	System	14 Oct 2020 19:17:40
User entered 'COPD'	Jennifer Leyva (b) (4) (b) (4)	14 Oct 2020 19:16:44

FDA-CBER-2022-1614-0004430

US3012098
Folder: Screening
Form: Medical History (24)
Generated On: 09 Jun 2021 14:54:12
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'UN Mar 2018'	Jennifer Leyva (b) (4) (b) (4)	14 Oct 2020 19:16:44

FDA-CBER-2022-1614-0004431

US3012098
Folder: Screening
Form: Medical History (24)
Generated On: 09 Jun 2021 14:54:12
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	14 Oct 2020 19:16:44

FDA-CBER-2022-1614-0004432

US3012098
Folder: Screening
Form: Medical History (24)
Generated On: 09 Jun 2021 14:54:12
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	14 Oct 2020 19:16:44

FDA-CBER-2022-1614-0004433

US3012098
Folder: Screening
Form: Medical History (24)
Generated On: 09 Jun 2021 14:54:12
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	14 Oct 2020 19:16:44

FDA-CBER-2022-1614-0004434

US3012098
Folder: Screening
Form: Medical History (24)
Generated On: 09 Jun 2021 14:54:12
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	14 Oct 2020 19:16:44

FDA-CBER-2022-1614-0004435

US3012098
Folder: Screening
Form: Medical History (24)
Generated On: 09 Jun 2021 14:54:12
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered 'Mar 2018'	System	14 Oct 2020 19:16:44

FDA-CBER-2022-1614-0004436

US3012098
Folder: Screening
Form: Medical History (24)
Generated On: 09 Jun 2021 14:54:12
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '2018'	System	14 Oct 2020 19:16:44

FDA-CBER-2022-1614-0004437

US3012098
Folder: Screening
Form: Medical History (24)
Generated On: 09 Jun 2021 14:54:12
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	14 Oct 2020 19:16:44

FDA-CBER-2022-1614-0004438

US3012098
Folder: Screening
Form: Medical History (24)
Generated On: 09 Jun 2021 14:54:12
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	14 Oct 2020 19:16:44

FDA-CBER-2022-1614-0004439

US3012098
Folder: Screening
Form: Medical History (25)
Generated On: 09 Jun 2021 14:54:12
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User closed query 'Per CDM, DM CLR re-query: Response noted. Kindly provide an explanation for no medical treatment. Thank you. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Feb 2021 08:48:59
Query 'Per CDM, DM CLR re-query: Response noted. Kindly provide an explanation for no medical treatment. Thank you. ' answered with 'Unknown. Subject has withdrawn and no further information can be collected.' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	22 Jan 2021 18:33:20
User opened query 'Per CDM, DM CLR re-query: Response noted. Kindly provide an explanation for no medical treatment. Thank you. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	22 Jan 2021 13:42:00
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	22 Jan 2021 13:24:23
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'Correct. No med taken to treat at time of participation.' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	21 Jan 2021 16:16:01
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	05 Jan 2021 00:00:48
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure congestive, LLT: Congestive heart failure - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 04:05:00
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 04:05:00

US3012098
Folder: Screening
Form: Medical History (25)
Generated On: 09 Jun 2021 14:54:12
Condition

Audit	User	Time (GMT)
Data point term sent to Coder	System	18 Nov 2020 21:19:41
User entered 'Diastolic Congestive Heart Failure'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:19:07

FDA-CBER-2022-1614-0004441

US3012098
Folder: Screening
Form: Medical History (25)
Generated On: 09 Jun 2021 14:54:12
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'UN UNK 2019'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:19:07

FDA-CBER-2022-1614-0004442

US3012098
Folder: Screening
Form: Medical History (25)
Generated On: 09 Jun 2021 14:54:12
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:19:07

FDA-CBER-2022-1614-0004443

US3012098
Folder: Screening
Form: Medical History (25)
Generated On: 09 Jun 2021 14:54:12
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:19:07

FDA-CBER-2022-1614-0004444

US3012098
Folder: Screening
Form: Medical History (25)
Generated On: 09 Jun 2021 14:54:12
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:19:07

FDA-CBER-2022-1614-0004445

US3012098
Folder: Screening
Form: Medical History (25)
Generated On: 09 Jun 2021 14:54:12
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:19:07

FDA-CBER-2022-1614-0004446

US3012098
Folder: Screening
Form: Medical History (25)
Generated On: 09 Jun 2021 14:54:12
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered 'Jan 2019'	System	18 Nov 2020 21:19:07

FDA-CBER-2022-1614-0004447

US3012098
Folder: Screening
Form: Medical History (25)
Generated On: 09 Jun 2021 14:54:12
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '2019'	System	18 Nov 2020 21:19:07

FDA-CBER-2022-1614-0004448

US3012098
Folder: Screening
Form: Medical History (25)
Generated On: 09 Jun 2021 14:54:12
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	18 Nov 2020 21:19:07

FDA-CBER-2022-1614-0004449

US3012098
Folder: Screening
Form: Medical History (25)
Generated On: 09 Jun 2021 14:54:12
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	18 Nov 2020 21:19:07

FDA-CBER-2022-1614-0004450

US3012098
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:54:12
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:21:27

FDA-CBER-2022-1614-0004451

US3012098
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:54:12
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '10 Aug 2020'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:21:27

US3012098
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:54:12
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '17:27'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:21:27

FDA-CBER-2022-1614-0004453

US3012098
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:54:12
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '10 Aug 2020 17:27'	(b) (4), (b) (6) System	11 Aug 2020 01:21:27

FDA-CBER-2022-1614-0004454

US3012098
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:54:12
Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4), (b) (6)	05 Mar 2021 19:09:37
User entered '62.0' in	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:21:27
DataPoint set to visible.	System	11 Aug 2020 00:33:10

FDA-CBER-2022-1614-0004455

US3012098
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:54:12
Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '182.6' lb	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:21:27
DataPoint set to visible.	System	11 Aug 2020 00:33:10

FDA-CBER-2022-1614-0004456

US3012098
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:54:12
BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
Amendment Manager: User entered '33.46781'	System	16 Sep 2020 23:50:57
User entered '33.5'	System	11 Aug 2020 01:21:27
DataPoint set to visible.	System	11 Aug 2020 00:33:10

FDA-CBER-2022-1614-0004457

US3012098
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:54:12
BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered 'kg/m2'	System	11 Aug 2020 01:21:27
DataPoint set to visible.	System	11 Aug 2020 00:33:10

FDA-CBER-2022-1614-0004458

US3012098
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:54:12
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered missing code ND - Not Done; reason for change New Information	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:18:09
User entered '98.4' F	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:21:27

US3012098
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:54:12
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty; reason for change New Information	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:18:09
User entered 'Oral (Oral)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:21:27

US3012098
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:54:12
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:21:27

FDA-CBER-2022-1614-0004461

US3012098
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:54:12
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered missing code ND - Not Done; reason for change New Information	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:18:09
User entered '92'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:21:27

US3012098
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:54:12
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered 'bpm'	System	11 Aug 2020 01:21:27

FDA-CBER-2022-1614-0004463

US3012098
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:54:12
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered missing code ND - Not Done; reason for change New Information	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:18:09
User entered '12'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:21:27

FDA-CBER-2022-1614-0004464

US3012098
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:54:12
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered 'breaths/min'	System	11 Aug 2020 01:21:27

FDA-CBER-2022-1614-0004465

US3012098
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:54:12
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered missing code ND - Not Done; reason for change New Information	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:18:09
User entered '106'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:21:27

FDA-CBER-2022-1614-0004466

US3012098
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:54:12
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered 'mmHg'	System	11 Aug 2020 01:21:27

FDA-CBER-2022-1614-0004467

US3012098
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:54:12
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered missing code ND - Not Done; reason for change New Information	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:18:09
User entered '88'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:21:27

FDA-CBER-2022-1614-0004468

US3012098
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:54:12
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered 'mmHg'	System	11 Aug 2020 01:21:27

FDA-CBER-2022-1614-0004469

US3012098
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:54:12
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09

FDA-CBER-2022-1614-0004470

US3012098
Folder: Screening
Form: Vital Signs
Generated On: 09 Jun 2021 14:54:12
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09

FDA-CBER-2022-1614-0004471

US3012098
Folder: Screening
Form: Physical Examination
Generated On: 09 Jun 2021 14:54:12
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:22:15

FDA-CBER-2022-1614-0004472

US3012098
Folder: Screening
Form: Physical Examination
Generated On: 09 Jun 2021 14:54:12
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	11 Sep 2020 09:47:45
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	08 Sep 2020 13:13:43
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	11 Aug 2020 01:22:22
User closed query 'The physical examination date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	11 Aug 2020 01:22:22
User entered '10 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:22:22
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	11 Aug 2020 01:22:15
User opened query 'The physical examination date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	11 Aug 2020 01:22:15
User entered '10 Apr 2020'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:22:15

FDA-CBER-2022-1614-0004473

US3012098
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 14:54:12
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '10 Aug 2020'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:23:46

FDA-CBER-2022-1614-0004474

US3012098
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 14:54:12
Is the participant of childbearing potential?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:23:46

FDA-CBER-2022-1614-0004475

US3012098
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 14:54:12
If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Post-menopausal (POST-MENOPAUSAL)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:23:46

FDA-CBER-2022-1614-0004476

US3012098
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 14:54:12
If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:23:46

FDA-CBER-2022-1614-0004477

US3012098
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 14:54:12
If Surgically sterile, date of surgery *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:23:46

FDA-CBER-2022-1614-0004478

US3012098
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 14:54:12
Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:23:46

FDA-CBER-2022-1614-0004479

US3012098
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 14:54:12
If Post-menopausal, date of last menstruation *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User closed query 'Per DM CLR: Please review date of last menstruation as a different start date of post menopausal is recorded in MH. Review if dates should be reconciled. Else, provide clarification on different dates.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	31 Aug 2020 08:26:10
Query 'Per DM CLR: Please review date of last menstruation as a different start date of post menopausal is recorded in MH. Review if dates should be reconciled. Else, provide clarification on different dates.' answered with 'Per PI, postmenopausal status is reached once without menses for one year.' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	27 Aug 2020 14:10:12
User opened query 'Per DM CLR: Please review date of last menstruation as a different start date of post menopausal is recorded in MH. Review if dates should be reconciled. Else, provide clarification on different dates.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	26 Aug 2020 11:27:31
User entered 'un UNK 2004'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:23:46

FDA-CBER-2022-1614-0004480

US3012098
Folder: Screening
Form: Childbearing Potential
Generated On: 09 Jun 2021 14:54:12
Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:23:46

FDA-CBER-2022-1614-0004481

US3012098
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:54:12
Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:24:44

FDA-CBER-2022-1614-0004482

US3012098
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:54:12
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:24:44

FDA-CBER-2022-1614-0004483

US3012098

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:54:12

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) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:24:44

US3012098

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:54:12

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) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:24:44

US3012098
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:54:12
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:24:44

US3012098

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:54:12

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) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:24:44

US3012098

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:54:12

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) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:24:44

US3012098
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:54:12
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) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:24:44

FDA-CBER-2022-1614-0004489

US3012098
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:54:12
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) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:24:44

FDA-CBER-2022-1614-0004490

US3012098
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:54:12
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) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:24:44

FDA-CBER-2022-1614-0004491

US3012098

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:54:12

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) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:24:44

US3012098
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:54:12
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:24:44

FDA-CBER-2022-1614-0004493

US3012098
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:54:12
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:24:44

FDA-CBER-2022-1614-0004494

US3012098
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:54:12
No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:24:44

FDA-CBER-2022-1614-0004495

US3012098
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:54:12
Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:24:44

FDA-CBER-2022-1614-0004496

US3012098

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:54:12

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) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:24:44

US3012098
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:54:12
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) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '1'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:24:44

FDA-CBER-2022-1614-0004498

US3012098

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:54:12

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) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:24:44

US3012098
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:54:12
Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:24:44

FDA-CBER-2022-1614-0004500

US3012098
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:54:12
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:24:44

FDA-CBER-2022-1614-0004501

US3012098
Folder: Screening
Form: Risk of Exposure
Generated On: 09 Jun 2021 14:54:12
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:24:44

FDA-CBER-2022-1614-0004502

US3012098
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 14:54:12
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:25:02

FDA-CBER-2022-1614-0004503

US3012098
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 14:54:12
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '10 Aug 2020'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:25:02

FDA-CBER-2022-1614-0004504

US3012098
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 14:54:12
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Clinic (Clinic)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:25:02

FDA-CBER-2022-1614-0004505

US3012098
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 09 Jun 2021 14:54:12
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User entered 'VISIT1'	System	11 Aug 2020 01:25:02

FDA-CBER-2022-1614-0004506

US3012098
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 14:54:12
What was the date of randomization? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '10 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	10 Aug 2020 23:44:16

FDA-CBER-2022-1614-0004507

US3012098

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:54:12

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 03:27:30
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:27:30
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Aug 2020 23:44:16
User entered '143598' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	10 Aug 2020 23:44:16

US3012098
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 14:54:12
In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	10 Aug 2020 23:44:16

FDA-CBER-2022-1614-0004509

US3012098

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:54:12

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) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	11 Aug 2020 14:05:11

US3012098

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:54:12

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) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'No (N)'	Katherine Davis (b) (4) (b) (4)	11 Aug 2020 14:05:11

US3012098
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 14:54:12
Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'No (N)'	Katherine Davis (b) (4) (b) (4)	11 Aug 2020 14:05:11

FDA-CBER-2022-1614-0004512

US3012098
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 14:54:12
Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'No (N)'	Katherine Davis (b) (4) (b) (4)	11 Aug 2020 14:05:11

FDA-CBER-2022-1614-0004513

US3012098
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 14:54:12
Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'No (N)'	Katherine Davis (b) (4) (b) (4)	11 Aug 2020 14:05:11

FDA-CBER-2022-1614-0004514

US3012098
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 09 Jun 2021 14:54:12
Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	30 Oct 2020 06:04:27
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'updated' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	28 Oct 2020 14:12:36
User entered 'No (N)'	Jennifer Leyva (b) (4)	28 Oct 2020 14:12:34
User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Oct 2020 11:49:56
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:17:08
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:24:17

FDA-CBER-2022-1614-0004515

US3012098
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 14:54:12
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered missing code ND - Not Done; reason for change New Information	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:18:26
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:26:46

US3012098
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 14:54:12
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered missing code ND - Not Done; reason for change New Information	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:18:26
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:26:46

FDA-CBER-2022-1614-0004517

US3012098
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 14:54:12
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered missing code ND - Not Done; reason for change New Information	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:18:26
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:26:46

FDA-CBER-2022-1614-0004518

US3012098
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 14:54:12
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered missing code ND - Not Done; reason for change New Information	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:18:26
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:26:46

FDA-CBER-2022-1614-0004519

US3012098
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:54:12
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:26:46

FDA-CBER-2022-1614-0004520

US3012098
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:54:12
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:26:46

FDA-CBER-2022-1614-0004521

US3012098
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:54:12
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '10 Aug 2020'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:26:46

FDA-CBER-2022-1614-0004522

US3012098
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:54:12
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '17:27'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:26:46

FDA-CBER-2022-1614-0004523

US3012098
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:54:12
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User entered '10 Aug 2020 17:27'	(b) (4), (b) (6) System	11 Aug 2020 01:26:46

FDA-CBER-2022-1614-0004524

US3012098
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:54:12
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '98.4' F	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:26:46

FDA-CBER-2022-1614-0004525

US3012098
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:54:12
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Oral (Oral)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:26:46

FDA-CBER-2022-1614-0004526

US3012098
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:54:12
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:26:46

FDA-CBER-2022-1614-0004527

US3012098
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:54:12
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User closed query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 01:27:09
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	11 Aug 2020 01:27:09
User entered '92' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:27:09
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 01:26:46
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:26:46

FDA-CBER-2022-1614-0004528

US3012098
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:54:12
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User entered 'bpm'	System	11 Aug 2020 01:27:09
User entered empty.	System	11 Aug 2020 01:26:46

FDA-CBER-2022-1614-0004529

US3012098
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:54:12
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User closed query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 01:27:09
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	11 Aug 2020 01:27:09
User entered '12' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:27:09
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 01:26:46
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:26:46

US3012098
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:54:12
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User entered 'breaths/min'	System	11 Aug 2020 01:27:09
User entered empty.	System	11 Aug 2020 01:26:46

FDA-CBER-2022-1614-0004531

US3012098
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:54:12
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User closed query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 01:27:09
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	11 Aug 2020 01:27:09
User entered '106' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:27:09
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 01:26:46
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:26:46

FDA-CBER-2022-1614-0004532

US3012098
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:54:12
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User entered 'mmHg'	System	11 Aug 2020 01:27:09
User entered empty.	System	11 Aug 2020 01:26:46

FDA-CBER-2022-1614-0004533

US3012098
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:54:12
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User closed query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 01:27:09
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	11 Aug 2020 01:27:09
User entered '88' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:27:09
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 01:26:46
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:26:46

FDA-CBER-2022-1614-0004534

US3012098
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:54:12
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User entered 'mmHg'	System	11 Aug 2020 01:27:09
User entered empty.	System	11 Aug 2020 01:26:46

FDA-CBER-2022-1614-0004535

US3012098
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 14:54:12
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered missing code ND - Not Done; reason for change New Information	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:18:26
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:26:46

US3012098
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 09 Jun 2021 14:54:12
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered missing code ND - Not Done; reason for change New Information	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:18:26
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:26:46

FDA-CBER-2022-1614-0004537

US3012098
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:54:12
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:26:46

FDA-CBER-2022-1614-0004538

US3012098
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:54:12
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:26:46

FDA-CBER-2022-1614-0004539

US3012098
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:54:12
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '10 Aug 2020'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:26:46

FDA-CBER-2022-1614-0004540

US3012098
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:54:12
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Aug 2020 10:42:08
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'per protocol post dose vitals are collected 30 minutes post vaccination.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:27:37
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	System	11 Aug 2020 01:26:46
User entered '19:46'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:26:46

FDA-CBER-2022-1614-0004541

US3012098
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:54:12
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User entered '10 Aug 2020 19:46'	(b) (4), (b) (6) System	11 Aug 2020 01:26:46

FDA-CBER-2022-1614-0004542

US3012098
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:54:12
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '98.1' F	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:26:46

FDA-CBER-2022-1614-0004543

US3012098
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:54:12
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Oral (Oral)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:26:46

FDA-CBER-2022-1614-0004544

US3012098
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:54:12
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:26:46

FDA-CBER-2022-1614-0004545

US3012098
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:54:12
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User closed query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 01:27:57
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	11 Aug 2020 01:27:57
User entered '82' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:27:57
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 01:26:46
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:26:46

FDA-CBER-2022-1614-0004546

US3012098
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:54:12
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User entered 'bpm'	System	11 Aug 2020 01:27:57
User entered empty.	System	11 Aug 2020 01:26:46

FDA-CBER-2022-1614-0004547

US3012098
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:54:12
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User closed query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 01:27:57
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	11 Aug 2020 01:27:57
User entered '14' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:27:57
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 01:26:46
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:26:46

FDA-CBER-2022-1614-0004548

US3012098
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:54:12
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User entered 'breaths/min'	System	11 Aug 2020 01:27:57
User entered empty.	System	11 Aug 2020 01:26:46

FDA-CBER-2022-1614-0004549

US3012098
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:54:12
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User closed query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 01:27:57
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	11 Aug 2020 01:27:57
User entered '120' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:27:57
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 01:26:46
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:26:46

FDA-CBER-2022-1614-0004550

US3012098
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:54:12
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User entered 'mmHg'	System	11 Aug 2020 01:27:57
User entered empty.	System	11 Aug 2020 01:26:46

FDA-CBER-2022-1614-0004551

US3012098
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:54:12
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User closed query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 01:27:57
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	11 Aug 2020 01:27:57
User entered '80' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:27:57
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Aug 2020 01:26:46
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:26:46

FDA-CBER-2022-1614-0004552

US3012098
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:54:12
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User entered 'mmHg'	System	11 Aug 2020 01:27:57
User entered empty.	System	11 Aug 2020 01:26:46

US3012098
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 09 Jun 2021 14:54:12
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User closed query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	System	08 Sep 2020 13:18:43
User opened query 'Was the physical examination performed is No, however Date of examination is provided. Please correct.' (Site from System).	System	08 Sep 2020 13:18:36
User entered 'No (N)' reason for change: New Information	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:18:36
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:28:09

FDA-CBER-2022-1614-0004554

US3012098
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 09 Jun 2021 14:54:12
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty; reason for change New Information	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:18:43
User entered '10 Aug 2020'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:28:09

FDA-CBER-2022-1614-0004555

US3012098
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 14:54:12
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004556

US3012098
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 14:54:12
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004557

US3012098

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:54:12

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) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	11 Aug 2020 00:33:30

US3012098
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 14:54:12
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered 'MRNA-1273 OR PLACEBO'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004559

US3012098
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 14:54:12
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '10 Aug 2020'	Jennifer Leyva (b) (4) (b) (4)	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004560

US3012098
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 14:54:12
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '19:13'	Jennifer Leyva (b) (4) (b) (4)	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004561

US3012098
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 14:54:12
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '10 Aug 2020 19:13'	(b) (4), (b) (6) System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004562

US3012098
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 14:54:12
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Left Arm (LEFT ARM)'	Jennifer Leyva (b) (4) (b) (4)	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004563

US3012098
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 14:54:12
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered 'ONCE'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004564

US3012098
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 09 Jun 2021 14:54:12
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered 'INTRAMUSCULAR'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004565

US3012098
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 14:54:12
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:29:06

FDA-CBER-2022-1614-0004566

US3012098
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 14:54:12
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '10 Aug 2020'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:29:06

FDA-CBER-2022-1614-0004567

US3012098
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 14:54:12
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '18:06'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:29:06

FDA-CBER-2022-1614-0004568

US3012098
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 14:54:12
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '10 Aug 2020 18:06'	(b) (4), (b) (6) System	11 Aug 2020 01:29:06

FDA-CBER-2022-1614-0004569

US3012098
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 09 Jun 2021 14:54:12
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '10 Aug 2020'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:29:36

US3012098
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 14:54:12
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:29:36

FDA-CBER-2022-1614-0004571

US3012098
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 14:54:12
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:29:36

FDA-CBER-2022-1614-0004572

US3012098
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 14:54:12
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '18:33'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:29:36

FDA-CBER-2022-1614-0004573

US3012098
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 14:54:12
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '10 Aug 2020 18:33'	(b) (4), (b) (6) System	11 Aug 2020 01:29:36

FDA-CBER-2022-1614-0004574

US3012098
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 14:54:12
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:29:36

FDA-CBER-2022-1614-0004575

US3012098
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 14:54:12
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:29:36

FDA-CBER-2022-1614-0004576

US3012098
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 14:54:12
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:29:36

FDA-CBER-2022-1614-0004577

US3012098
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 14:54:12
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	11 Aug 2020 01:29:36

FDA-CBER-2022-1614-0004578

US3012098
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 09 Jun 2021 14:54:12
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:29:43

FDA-CBER-2022-1614-0004579

US3012098
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 09 Jun 2021 14:54:12
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '1'	(b) (4), (b) (6) System	11 Aug 2020 01:29:43

FDA-CBER-2022-1614-0004580

US3012098
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 14:54:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
Data entry locked.	System	11 Aug 2020 00:33:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004581

US3012098
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 14:54:12
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-10T19:46:00', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '6be01292-0f1d-4b31-8e1b-69b2ab4ef969'	System	11 Aug 2020 00:46:33
User entered 'Yes (Y)'	System	11 Aug 2020 00:46:33

FDA-CBER-2022-1614-0004582

US3012098
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 14:54:12
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-10T19:46:07', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '6be01292-0f1d-4b31-8e1b-69b2ab4ef969'	System	11 Aug 2020 00:46:33
User entered '98.1'	System	11 Aug 2020 00:46:33

FDA-CBER-2022-1614-0004583

US3012098
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 14:54:12
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-10T19:46:13', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '6be01292-0f1d-4b31-8e1b-69b2ab4ef969'	System	11 Aug 2020 00:46:33
User entered 'No (N)'	System	11 Aug 2020 00:46:33

FDA-CBER-2022-1614-0004584

US3012098
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 14:54:12
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-10T19:46:24', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '6be01292-0f1d-4b31-8e1b-69b2ab4ef969'	System	11 Aug 2020 00:46:33
User entered '10 Aug 2020 19:46'	System	11 Aug 2020 00:46:33

FDA-CBER-2022-1614-0004585

US3012098
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 14:54:12
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '10 Aug 2020 19:33'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004586

US3012098
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 14:54:12
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '10 Aug 2020 22:03'	(b) (4), (b) (6) System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004587

US3012098
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 14:54:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
Data entry locked.	System	11 Aug 2020 00:33:30
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004588

US3012098
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 14:54:12
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13

FDA-CBER-2022-1614-0004589

US3012098
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 14:54:12
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13

FDA-CBER-2022-1614-0004590

US3012098
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 14:54:12
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13

FDA-CBER-2022-1614-0004591

US3012098
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 14:54:12
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13

FDA-CBER-2022-1614-0004592

US3012098
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 14:54:12
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13

FDA-CBER-2022-1614-0004593

US3012098
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 14:54:12
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13

FDA-CBER-2022-1614-0004594

US3012098
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 14:54:12
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '10 Aug 2020 22:58'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004595

US3012098
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 14:54:12
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '11 Aug 2020 11:59'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004596

US3012098
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:54:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
Data entry locked.	System	11 Aug 2020 00:33:30
User entered 'Day 2'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004597

US3012098
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:54:12
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-11T13:35:29', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '9c20e064-d651-448a-9cea-efa369ef8677'	System	11 Aug 2020 18:36:14
User entered 'Yes (Y)'	System	11 Aug 2020 18:36:14

FDA-CBER-2022-1614-0004598

US3012098
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:54:12
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-11T13:35:55', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '9c20e064-d651-448a-9cea-efa369ef8677'	System	11 Aug 2020 18:36:14
User entered '98.7'	System	11 Aug 2020 18:36:14

FDA-CBER-2022-1614-0004599

US3012098
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:54:12
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-11T13:35:59', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '9c20e064-d651-448a-9cea-efa369ef8677'	System	11 Aug 2020 18:36:14
User entered 'No (N)'	System	11 Aug 2020 18:36:14

FDA-CBER-2022-1614-0004600

US3012098
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:54:12
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-11T13:36:07', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '9c20e064-d651-448a-9cea-efa369ef8677'	System	11 Aug 2020 18:36:14
User entered '11 Aug 2020 13:36'	System	11 Aug 2020 18:36:14

FDA-CBER-2022-1614-0004601

US3012098
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:54:12
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '11 Aug 2020 12:00'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004602

US3012098
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:54:12
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004603

US3012098
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:54:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
Data entry locked.	System	11 Aug 2020 00:33:30
User entered 'Day 3'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004604

US3012098
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:54:12
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-12T17:31:20', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '57947b7e-c952-4fb3-ae30-0dc67b322eba'	System	12 Aug 2020 22:31:53
User entered 'Yes (Y)'	System	12 Aug 2020 22:31:53

FDA-CBER-2022-1614-0004605

US3012098
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:54:12
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-12T17:31:28', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '57947b7e-c952-4fb3-ae30-0dc67b322eba'	System	12 Aug 2020 22:31:53
User entered '98.3'	System	12 Aug 2020 22:31:53

FDA-CBER-2022-1614-0004606

US3012098
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:54:12
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-12T17:31:34', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '57947b7e-c952-4fb3-ae30-0dc67b322eba'	System	12 Aug 2020 22:31:53
User entered 'No (N)'	System	12 Aug 2020 22:31:53

FDA-CBER-2022-1614-0004607

US3012098
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:54:12
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-12T17:31:49', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '57947b7e-c952-4fb3-ae30-0dc67b322eba'	System	12 Aug 2020 22:31:53
User entered '12 Aug 2020 17:31'	System	12 Aug 2020 22:31:53

FDA-CBER-2022-1614-0004608

US3012098
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:54:12
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004609

US3012098
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:54:12
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004610

US3012098
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 14:54:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
Data entry locked.	System	11 Aug 2020 00:33:30
User entered 'Day 4'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004611

US3012098
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 14:54:12
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-13T19:03:45', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'd3dd55d9-e095-4a4e-983a-fb0bd4840993'	System	14 Aug 2020 00:04:12
User entered 'Yes (Y)'	System	14 Aug 2020 00:04:12

FDA-CBER-2022-1614-0004612

US3012098
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 14:54:12
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-13T19:03:55', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'd3dd55d9-e095-4a4e-983a-fb0bd4840993'	System	14 Aug 2020 00:04:12
User entered '97.0'	System	14 Aug 2020 00:04:12

FDA-CBER-2022-1614-0004613

US3012098
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 14:54:12
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-13T19:04:01', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'd3dd55d9-e095-4a4e-983a-fb0bd4840993'	System	14 Aug 2020 00:04:12
User entered 'No (N)'	System	14 Aug 2020 00:04:12

FDA-CBER-2022-1614-0004614

US3012098
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 14:54:12
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-13T19:04:08', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'd3dd55d9-e095-4a4e-983a-fb0bd4840993'	System	14 Aug 2020 00:04:12
User entered '13 Aug 2020 19:04'	System	14 Aug 2020 00:04:12

FDA-CBER-2022-1614-0004615

US3012098
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 14:54:12
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004616

US3012098
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 14:54:12
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004617

US3012098
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:54:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
Data entry locked.	System	11 Aug 2020 00:33:30
User entered 'Day 5'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004618

US3012098
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:54:12
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-14T18:13:35', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'e8503204-5113-4292-90d3-1031f7c7edaa'	System	14 Aug 2020 23:13:54
User entered 'Yes (Y)'	System	14 Aug 2020 23:13:54

FDA-CBER-2022-1614-0004619

US3012098
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:54:12
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-14T18:13:42', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'e8503204-5113-4292-90d3-1031f7c7edaa'	System	14 Aug 2020 23:13:54
User entered '97.9'	System	14 Aug 2020 23:13:54

FDA-CBER-2022-1614-0004620

US3012098
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:54:12
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-14T18:13:46', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'e8503204-5113-4292-90d3-1031f7c7edaa'	System	14 Aug 2020 23:13:54
User entered 'No (N)'	System	14 Aug 2020 23:13:54

FDA-CBER-2022-1614-0004621

US3012098
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:54:12
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-14T18:13:52', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'e8503204-5113-4292-90d3-1031f7c7edaa'	System	14 Aug 2020 23:13:54
User entered '14 Aug 2020 18:13'	System	14 Aug 2020 23:13:54

FDA-CBER-2022-1614-0004622

US3012098
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:54:12
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004623

US3012098
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:54:12
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004624

US3012098
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:54:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
Data entry locked.	System	11 Aug 2020 00:33:30
User entered 'Day 6'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004625

US3012098
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:54:12
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-15T18:43:21', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '40da028d-c99a-42fe-838f-52029b1aa586'	System	15 Aug 2020 23:43:43
User entered 'Yes (Y)'	System	15 Aug 2020 23:43:43

FDA-CBER-2022-1614-0004626

US3012098
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:54:12
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-15T18:43:28', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '40da028d-c99a-42fe-838f-52029b1aa586'	System	15 Aug 2020 23:43:43
User entered '96.8'	System	15 Aug 2020 23:43:43

FDA-CBER-2022-1614-0004627

US3012098
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:54:12
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-15T18:43:32', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '40da028d-c99a-42fe-838f-52029b1aa586'	System	15 Aug 2020 23:43:43
User entered 'No (N)'	System	15 Aug 2020 23:43:43

FDA-CBER-2022-1614-0004628

US3012098
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:54:12
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-15T18:43:39', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '40da028d-c99a-42fe-838f-52029b1aa586'	System	15 Aug 2020 23:43:43
User entered '15 Aug 2020 18:43'	System	15 Aug 2020 23:43:43

FDA-CBER-2022-1614-0004629

US3012098
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:54:12
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004630

US3012098
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:54:12
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004631

US3012098
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:54:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
Data entry locked.	System	11 Aug 2020 00:33:30
User entered 'Day 7'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004632

US3012098
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:54:12
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-16T23:45:25', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '9fb0d092-0ef5-4079-b1f0-7cda3d1701a1'	System	17 Aug 2020 04:45:55
User entered 'Yes (Y)'	System	17 Aug 2020 04:45:55

FDA-CBER-2022-1614-0004633

US3012098
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:54:12
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-16T23:45:42', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '9fb0d092-0ef5-4079-b1f0-7cda3d1701a1'	System	17 Aug 2020 04:45:55
User entered '96.8'	System	17 Aug 2020 04:45:55

FDA-CBER-2022-1614-0004634

US3012098
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:54:12
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-16T23:45:45', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '9fb0d092-0ef5-4079-b1f0-7cda3d1701a1'	System	17 Aug 2020 04:45:55
User entered 'No (N)'	System	17 Aug 2020 04:45:55

FDA-CBER-2022-1614-0004635

US3012098
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:54:12
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-16T23:45:51', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '9fb0d092-0ef5-4079-b1f0-7cda3d1701a1'	System	17 Aug 2020 04:45:55
User entered '16 Aug 2020 23:45'	System	17 Aug 2020 04:45:55

FDA-CBER-2022-1614-0004636

US3012098
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:54:12
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004637

US3012098
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:54:12
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004638

US3012098
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:54:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
Data entry locked.	System	11 Aug 2020 00:33:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004639

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:54:12

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-10T19:46:45', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'fcd10577-7b0f-4744-a547-0d79143689c2'	System	11 Aug 2020 00:47:12
User entered 'None (1)'	System	11 Aug 2020 00:47:12

US3012098
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:54:12
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-10T19:46:49', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'fcd10577-7b0f-4744-a547-0d79143689c2'	System	11 Aug 2020 00:47:12
User entered 'No (N)'	System	11 Aug 2020 00:47:12

FDA-CBER-2022-1614-0004641

US3012098
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:54:12
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-10T19:46:52', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'fcd10577-7b0f-4744-a547-0d79143689c2'	System	11 Aug 2020 00:47:12
User entered 'No (N)'	System	11 Aug 2020 00:47:12

FDA-CBER-2022-1614-0004642

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:54:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-10T19:46:58', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'fcd10577-7b0f-4744-a547-0d79143689c2'	System	11 Aug 2020 00:47:12
User entered 'None (1)'	System	11 Aug 2020 00:47:12

US3012098
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:54:12
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-10T19:47:06', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'fcd10577-7b0f-4744-a547-0d79143689c2'	System	11 Aug 2020 00:47:12
User entered '10 Aug 2020 19:47'	System	11 Aug 2020 00:47:12

FDA-CBER-2022-1614-0004644

US3012098
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:54:12
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '10 Aug 2020 19:33'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004645

US3012098
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:54:12
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '10 Aug 2020 22:03'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004646

US3012098
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:54:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
Data entry locked.	System	11 Aug 2020 00:33:30
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004647

US3012098
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:54:12
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13

FDA-CBER-2022-1614-0004648

US3012098
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:54:12
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13

FDA-CBER-2022-1614-0004649

US3012098
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:54:12
Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13

FDA-CBER-2022-1614-0004650

US3012098
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:54:12
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13

FDA-CBER-2022-1614-0004651

US3012098
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:54:12
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13

FDA-CBER-2022-1614-0004652

US3012098
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:54:12
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13

FDA-CBER-2022-1614-0004653

US3012098
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:54:12
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13

FDA-CBER-2022-1614-0004654

US3012098
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:54:12
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '10 Aug 2020 22:58'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004655

US3012098
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:54:12
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '11 Aug 2020 11:59'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004656

US3012098
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:54:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
Data entry locked.	System	11 Aug 2020 00:33:30
User entered 'Day 2'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004657

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:54:12

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-11T13:36:19', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '90e778fb-045a-44b6-9e4d-9dc4fb7f9116'	System	11 Aug 2020 18:36:50
User entered 'None (1)'	System	11 Aug 2020 18:36:50

US3012098
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:54:12
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-11T13:36:23', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '90e778fb-045a-44b6-9e4d-9dc4fb7f9116'	System	11 Aug 2020 18:36:50
User entered 'No (N)'	System	11 Aug 2020 18:36:50

FDA-CBER-2022-1614-0004659

US3012098
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:54:12
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-11T13:36:27', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '90e778fb-045a-44b6-9e4d-9dc4fb7f9116'	System	11 Aug 2020 18:36:50
User entered 'No (N)'	System	11 Aug 2020 18:36:50

FDA-CBER-2022-1614-0004660

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:54:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-11T13:36:32', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '90e778fb-045a-44b6-9e4d-9dc4fb7f9116'	System	11 Aug 2020 18:36:50
User entered 'None (1)'	System	11 Aug 2020 18:36:50

US3012098
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:54:12
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-11T13:36:40', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '90e778fb-045a-44b6-9e4d-9dc4fb7f9116'	System	11 Aug 2020 18:36:50
User entered '11 Aug 2020 13:36'	System	11 Aug 2020 18:36:50

FDA-CBER-2022-1614-0004662

US3012098
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:54:12
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '11 Aug 2020 12:00'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004663

US3012098
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:54:12
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004664

US3012098
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 14:54:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
Data entry locked.	System	11 Aug 2020 00:33:30
User entered 'Day 3'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004665

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:54:12

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-12T17:32:07', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'f270e1f0-83d5-46d7-b9ab-e1c9c03cc35e'	System	12 Aug 2020 22:32:34
User entered 'Does not interfere with activity (2)'	System	12 Aug 2020 22:32:34

US3012098
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 14:54:12
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-12T17:32:12', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'f270e1f0-83d5-46d7-b9ab-e1c9c03cc35e'	System	12 Aug 2020 22:32:34
User entered 'No (N)'	System	12 Aug 2020 22:32:34

FDA-CBER-2022-1614-0004667

US3012098
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 14:54:12
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-12T17:32:16', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'f270e1f0-83d5-46d7-b9ab-e1c9c03cc35e'	System	12 Aug 2020 22:32:34
User entered 'No (N)'	System	12 Aug 2020 22:32:34

FDA-CBER-2022-1614-0004668

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:54:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-12T17:32:20', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'f270e1f0-83d5-46d7-b9ab-e1c9c03cc35e'	System	12 Aug 2020 22:32:34
User entered 'None (1)'	System	12 Aug 2020 22:32:34

US3012098
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 14:54:12
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-12T17:32:29', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'f270e1f0-83d5-46d7-b9ab-e1c9c03cc35e'	System	12 Aug 2020 22:32:34
User entered '12 Aug 2020 17:32'	System	12 Aug 2020 22:32:34

FDA-CBER-2022-1614-0004670

US3012098
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 14:54:12
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004671

US3012098
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 14:54:12
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004672

US3012098
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:54:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
Data entry locked.	System	11 Aug 2020 00:33:30
User entered 'Day 4'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004673

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:54:12

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-13T19:04:15', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'a1ce7be2-6deb-4b5a-b2ce-c702f093b542'	System	14 Aug 2020 00:04:47
User entered 'None (1)'	System	14 Aug 2020 00:04:47

US3012098
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:54:12
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-13T19:04:19', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'a1ce7be2-6deb-4b5a-b2ce-c702f093b542'	System	14 Aug 2020 00:04:47
User entered 'No (N)'	System	14 Aug 2020 00:04:47

FDA-CBER-2022-1614-0004675

US3012098
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:54:12
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-13T19:04:23', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'a1ce7be2-6deb-4b5a-b2ce-c702f093b542'	System	14 Aug 2020 00:04:47
User entered 'No (N)'	System	14 Aug 2020 00:04:47

FDA-CBER-2022-1614-0004676

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:54:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-13T19:04:33', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'a1ce7be2-6deb-4b5a-b2ce-c702f093b542'	System	14 Aug 2020 00:04:47
User entered 'None (1)'	System	14 Aug 2020 00:04:47

US3012098
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:54:12
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-13T19:04:40', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'a1ce7be2-6deb-4b5a-b2ce-c702f093b542'	System	14 Aug 2020 00:04:47
User entered '13 Aug 2020 19:04'	System	14 Aug 2020 00:04:47

FDA-CBER-2022-1614-0004678

US3012098
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:54:12
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004679

US3012098
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:54:12
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004680

US3012098
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:54:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
Data entry locked.	System	11 Aug 2020 00:33:30
User entered 'Day 5'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004681

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:54:12

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-14T18:14:04', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '9cb78a99-9ee5-48e0-b481-d661ce2b1c71'	System	14 Aug 2020 23:14:34
User entered 'None (1)'	System	14 Aug 2020 23:14:34

US3012098
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:54:12
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-14T18:14:08', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '9cb78a99-9ee5-48e0-b481-d661ce2b1c71'	System	14 Aug 2020 23:14:34
User entered 'No (N)'	System	14 Aug 2020 23:14:34

FDA-CBER-2022-1614-0004683

US3012098
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:54:12
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-14T18:14:11', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '9cb78a99-9ee5-48e0-b481-d661ce2b1c71'	System	14 Aug 2020 23:14:34
User entered 'No (N)'	System	14 Aug 2020 23:14:34

FDA-CBER-2022-1614-0004684

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:54:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-14T18:14:16', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '9cb78a99-9ee5-48e0-b481-d661ce2b1c71'	System	14 Aug 2020 23:14:34
User entered 'None (1)'	System	14 Aug 2020 23:14:34

US3012098
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:54:12
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-14T18:14:30', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '9cb78a99-9ee5-48e0-b481-d661ce2b1c71'	System	14 Aug 2020 23:14:34
User entered '14 Aug 2020 18:14'	System	14 Aug 2020 23:14:34

FDA-CBER-2022-1614-0004686

US3012098
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:54:12
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004687

US3012098
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:54:12
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004688

US3012098
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:54:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
Data entry locked.	System	11 Aug 2020 00:33:30
User entered 'Day 6'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004689

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:54:12

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-15T18:43:50', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '93bb48b4-33f7-4c06-ac15-d476bedcb3a5'	System	15 Aug 2020 23:44:22
User entered 'None (1)'	System	15 Aug 2020 23:44:22

US3012098
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:54:12
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-15T18:43:58', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '93bb48b4-33f7-4c06-ac15-d476bedcb3a5'	System	15 Aug 2020 23:44:22
User entered 'No (N)'	System	15 Aug 2020 23:44:22

FDA-CBER-2022-1614-0004691

US3012098
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:54:12
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-15T18:44:03', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '93bb48b4-33f7-4c06-ac15-d476bedcb3a5'	System	15 Aug 2020 23:44:22
User entered 'No (N)'	System	15 Aug 2020 23:44:22

FDA-CBER-2022-1614-0004692

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:54:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-15T18:44:08', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '93bb48b4-33f7-4c06-ac15-d476bedcb3a5'	System	15 Aug 2020 23:44:22
User entered 'None (1)'	System	15 Aug 2020 23:44:22

US3012098
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:54:12
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-15T18:44:17', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '93bb48b4-33f7-4c06-ac15-d476bedcb3a5'	System	15 Aug 2020 23:44:22
User entered '15 Aug 2020 18:44'	System	15 Aug 2020 23:44:22

FDA-CBER-2022-1614-0004694

US3012098
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:54:12
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004695

US3012098
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:54:12
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004696

US3012098
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:54:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
Data entry locked.	System	11 Aug 2020 00:33:30
User entered 'Day 7'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004697

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:54:12

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-16T23:45:57', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '4243e24b-077e-4595-ba8f-a7da1f8e42e0'	System	17 Aug 2020 04:46:22
User entered 'None (1)'	System	17 Aug 2020 04:46:22

US3012098
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:54:12
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-16T23:46:01', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '4243e24b-077e-4595-ba8f-a7da1f8e42e0'	System	17 Aug 2020 04:46:22
User entered 'No (N)'	System	17 Aug 2020 04:46:22

FDA-CBER-2022-1614-0004699

US3012098
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:54:12
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-16T23:46:04', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '4243e24b-077e-4595-ba8f-a7da1f8e42e0'	System	17 Aug 2020 04:46:22
User entered 'No (N)'	System	17 Aug 2020 04:46:22

FDA-CBER-2022-1614-0004700

US3012098

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:54:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-16T23:46:09', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '4243e24b-077e-4595-ba8f-a7da1f8e42e0'	System	17 Aug 2020 04:46:22
User entered 'None (1)'	System	17 Aug 2020 04:46:22

US3012098
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:54:12
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-16T23:46:16', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '4243e24b-077e-4595-ba8f-a7da1f8e42e0'	System	17 Aug 2020 04:46:22
User entered '16 Aug 2020 23:46'	System	17 Aug 2020 04:46:22

FDA-CBER-2022-1614-0004702

US3012098
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:54:12
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004703

US3012098
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:54:12
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 00:33:30

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:54:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
Data entry locked.	System	11 Aug 2020 00:33:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004705

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:54:12
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-10T19:47:15', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '4a47b0ea-ece4-4ace-b706-9137fd326d87'	System	11 Aug 2020 00:47:56
User entered 'None (0)'	System	11 Aug 2020 00:47:56

FDA-CBER-2022-1614-0004706

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:54:12
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-10T19:47:19', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '4a47b0ea-ece4-4ace-b706-9137fd326d87'	System	11 Aug 2020 00:47:56
User entered 'None (0)'	System	11 Aug 2020 00:47:56

FDA-CBER-2022-1614-0004707

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:54:12
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-10T19:47:25', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '4a47b0ea-ece4-4ace-b706-9137fd326d87'	System	11 Aug 2020 00:47:56
User entered 'None (0)'	System	11 Aug 2020 00:47:56

FDA-CBER-2022-1614-0004708

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:54:12
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-10T19:47:30', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '4a47b0ea-ece4-4ace-b706-9137fd326d87'	System	11 Aug 2020 00:47:56
User entered 'None (0)'	System	11 Aug 2020 00:47:56

FDA-CBER-2022-1614-0004709

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:54:12
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-10T19:47:33', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '4a47b0ea-ece4-4ace-b706-9137fd326d87'	System	11 Aug 2020 00:47:56
User entered 'None (0)'	System	11 Aug 2020 00:47:56

FDA-CBER-2022-1614-0004710

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:54:12
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-10T19:47:36', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '4a47b0ea-ece4-4ace-b706-9137fd326d87'	System	11 Aug 2020 00:47:56
User entered 'None (0)'	System	11 Aug 2020 00:47:56

FDA-CBER-2022-1614-0004711

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:54:12
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) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-10T19:47:42', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '4a47b0ea-ece4-4ace-b706-9137fd326d87'	System	11 Aug 2020 00:47:56
User entered 'No (N)'	System	11 Aug 2020 00:47:56

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:54:12
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-10T19:47:50', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '4a47b0ea-ece4-4ace-b706-9137fd326d87'	System	11 Aug 2020 00:47:56
User entered '10 Aug 2020 19:47'	System	11 Aug 2020 00:47:56

FDA-CBER-2022-1614-0004713

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:54:12
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '10 Aug 2020 19:33'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004714

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:54:12
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '10 Aug 2020 22:03'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004715

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:54:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
Data entry locked.	System	11 Aug 2020 00:33:30
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004716

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:54:12
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13

FDA-CBER-2022-1614-0004717

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:54:12
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13

FDA-CBER-2022-1614-0004718

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:54:12
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13

FDA-CBER-2022-1614-0004719

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:54:12
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13

FDA-CBER-2022-1614-0004720

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:54:12
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13

FDA-CBER-2022-1614-0004721

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:54:12
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13

FDA-CBER-2022-1614-0004722

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:54:12
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) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13

FDA-CBER-2022-1614-0004723

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:54:12
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13

FDA-CBER-2022-1614-0004724

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:54:12
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '10 Aug 2020 22:58'	(b) (4), (b) (6) System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004725

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:54:12
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '11 Aug 2020 11:59'	(b) (4), (b) (6) System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004726

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:54:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
Data entry locked.	System	11 Aug 2020 00:33:30
User entered 'Day 2'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004727

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:54:12
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-11T13:36:47', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '79606267-1793-4984-98b7-7977a67380ae'	System	11 Aug 2020 18:37:25
User entered 'None (0)'	System	11 Aug 2020 18:37:25

FDA-CBER-2022-1614-0004728

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:54:12
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-11T13:36:50', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '79606267-1793-4984-98b7-7977a67380ae'	System	11 Aug 2020 18:37:25
User entered 'None (0)'	System	11 Aug 2020 18:37:25

FDA-CBER-2022-1614-0004729

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:54:12
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-11T13:36:55', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '79606267-1793-4984-98b7-7977a67380ae'	System	11 Aug 2020 18:37:25
User entered 'None (0)'	System	11 Aug 2020 18:37:25

FDA-CBER-2022-1614-0004730

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:54:12
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-11T13:36:59', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '79606267-1793-4984-98b7-7977a67380ae'	System	11 Aug 2020 18:37:25
User entered 'None (0)'	System	11 Aug 2020 18:37:25

FDA-CBER-2022-1614-0004731

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:54:12
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-11T13:37:02', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '79606267-1793-4984-98b7-7977a67380ae'	System	11 Aug 2020 18:37:25
User entered 'None (0)'	System	11 Aug 2020 18:37:25

FDA-CBER-2022-1614-0004732

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:54:12
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-11T13:37:07', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '79606267-1793-4984-98b7-7977a67380ae'	System	11 Aug 2020 18:37:25
User entered 'None (0)'	System	11 Aug 2020 18:37:25

FDA-CBER-2022-1614-0004733

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:54:12

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) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-11T13:37:11', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '79606267-1793-4984-98b7-7977a67380ae'	System	11 Aug 2020 18:37:25
User entered 'No (N)'	System	11 Aug 2020 18:37:25

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:54:12
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-11T13:37:19', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '79606267-1793-4984-98b7-7977a67380ae'	System	11 Aug 2020 18:37:25
User entered '11 Aug 2020 13:37'	System	11 Aug 2020 18:37:25

FDA-CBER-2022-1614-0004735

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:54:12
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '11 Aug 2020 12:00'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004736

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:54:12
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004737

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:54:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
Data entry locked.	System	11 Aug 2020 00:33:30
User entered 'Day 3'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004738

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:54:12
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-12T17:32:40', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '152cb0af-74a6-4f7d-a03c-a713f2bdb16e'	System	12 Aug 2020 22:33:21
User entered 'No interference with activity (1)'	System	12 Aug 2020 22:33:21

FDA-CBER-2022-1614-0004739

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:54:12
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-12T17:32:44', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '152cb0af-74a6-4f7d-a03c-a713f2bdb16e'	System	12 Aug 2020 22:33:21
User entered 'None (0)'	System	12 Aug 2020 22:33:21

FDA-CBER-2022-1614-0004740

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:54:12
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-12T17:32:50', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '152cb0af-74a6-4f7d-a03c-a713f2bdb16e'	System	12 Aug 2020 22:33:21
User entered 'None (0)'	System	12 Aug 2020 22:33:21

FDA-CBER-2022-1614-0004741

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:54:12
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-12T17:32:56', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '152cb0af-74a6-4f7d-a03c-a713f2bdb16e'	System	12 Aug 2020 22:33:21
User entered 'None (0)'	System	12 Aug 2020 22:33:21

FDA-CBER-2022-1614-0004742

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:54:12
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-12T17:32:59', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '152cb0af-74a6-4f7d-a03c-a713f2bdb16e'	System	12 Aug 2020 22:33:21
User entered 'None (0)'	System	12 Aug 2020 22:33:21

FDA-CBER-2022-1614-0004743

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:54:12
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-12T17:33:03', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '152cb0af-74a6-4f7d-a03c-a713f2bdb16e'	System	12 Aug 2020 22:33:21
User entered 'None (0)'	System	12 Aug 2020 22:33:21

FDA-CBER-2022-1614-0004744

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:54:12

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) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-12T17:33:08', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '152cb0af-74a6-4f7d-a03c-a713f2bdb16e'	System	12 Aug 2020 22:33:21
User entered 'No (N)'	System	12 Aug 2020 22:33:21

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:54:12
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-12T17:33:18', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '152cb0af-74a6-4f7d-a03c-a713f2bdb16e'	System	12 Aug 2020 22:33:21
User entered '12 Aug 2020 17:33'	System	12 Aug 2020 22:33:21

FDA-CBER-2022-1614-0004746

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:54:12
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004747

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:54:12
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004748

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:54:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
Data entry locked.	System	11 Aug 2020 00:33:30
User entered 'Day 4'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004749

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:54:12
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-13T19:04:47', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '77dfbee3-bd12-414b-a0ca-6599cc853455'	System	14 Aug 2020 00:05:39
User entered 'None (0)'	System	14 Aug 2020 00:05:39

FDA-CBER-2022-1614-0004750

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:54:12
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-13T19:04:55', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '77dfbee3-bd12-414b-a0ca-6599cc853455'	System	14 Aug 2020 00:05:39
User entered 'None (0)'	System	14 Aug 2020 00:05:39

FDA-CBER-2022-1614-0004751

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:54:12
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-13T19:05:00', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '77dfbee3-bd12-414b-a0ca-6599cc853455'	System	14 Aug 2020 00:05:39
User entered 'None (0)'	System	14 Aug 2020 00:05:39

FDA-CBER-2022-1614-0004752

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:54:12
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-13T19:05:06', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '77dfbee3-bd12-414b-a0ca-6599cc853455'	System	14 Aug 2020 00:05:39
User entered 'None (0)'	System	14 Aug 2020 00:05:39

FDA-CBER-2022-1614-0004753

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:54:12
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-13T19:05:10', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '77dfbee3-bd12-414b-a0ca-6599cc853455'	System	14 Aug 2020 00:05:39
User entered 'None (0)'	System	14 Aug 2020 00:05:39

FDA-CBER-2022-1614-0004754

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:54:12
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-13T19:05:15', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '77dfbee3-bd12-414b-a0ca-6599cc853455'	System	14 Aug 2020 00:05:39
User entered 'None (0)'	System	14 Aug 2020 00:05:39

FDA-CBER-2022-1614-0004755

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:54:12

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) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-13T19:05:24', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '77dfbee3-bd12-414b-a0ca-6599cc853455'	System	14 Aug 2020 00:05:39
User entered 'No (N)'	System	14 Aug 2020 00:05:39

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:54:12
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-13T19:05:33', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '77dfbee3-bd12-414b-a0ca-6599cc853455'	System	14 Aug 2020 00:05:39
User entered '13 Aug 2020 19:05'	System	14 Aug 2020 00:05:39

FDA-CBER-2022-1614-0004757

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:54:12
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004758

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:54:12
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004759

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:54:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
Data entry locked.	System	11 Aug 2020 00:33:30
User entered 'Day 5'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004760

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:54:12
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-14T18:14:40', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'c5ef893d-955b-4546-94ab-d5c8dd8b8923'	System	14 Aug 2020 23:15:14
User entered 'None (0)'	System	14 Aug 2020 23:15:14

FDA-CBER-2022-1614-0004761

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:54:12
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-14T18:14:43', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'c5ef893d-955b-4546-94ab-d5c8dd8b8923'	System	14 Aug 2020 23:15:14
User entered 'None (0)'	System	14 Aug 2020 23:15:14

FDA-CBER-2022-1614-0004762

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:54:12
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-14T18:14:46', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'c5ef893d-955b-4546-94ab-d5c8dd8b8923'	System	14 Aug 2020 23:15:14
User entered 'None (0)'	System	14 Aug 2020 23:15:14

FDA-CBER-2022-1614-0004763

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:54:12
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-14T18:14:50', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'c5ef893d-955b-4546-94ab-d5c8dd8b8923'	System	14 Aug 2020 23:15:14
User entered 'None (0)'	System	14 Aug 2020 23:15:14

FDA-CBER-2022-1614-0004764

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:54:12
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-14T18:14:53', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'c5ef893d-955b-4546-94ab-d5c8dd8b8923'	System	14 Aug 2020 23:15:14
User entered 'None (0)'	System	14 Aug 2020 23:15:14

FDA-CBER-2022-1614-0004765

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:54:12
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-14T18:14:56', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'c5ef893d-955b-4546-94ab-d5c8dd8b8923'	System	14 Aug 2020 23:15:14
User entered 'None (0)'	System	14 Aug 2020 23:15:14

FDA-CBER-2022-1614-0004766

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:54:12
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) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-14T18:15:01', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'c5ef893d-955b-4546-94ab-d5c8dd8b8923'	System	14 Aug 2020 23:15:14
User entered 'No (N)'	System	14 Aug 2020 23:15:14

FDA-CBER-2022-1614-0004767

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:54:12
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-14T18:15:11', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'c5ef893d-955b-4546-94ab-d5c8dd8b8923'	System	14 Aug 2020 23:15:14
User entered '14 Aug 2020 18:15'	System	14 Aug 2020 23:15:14

FDA-CBER-2022-1614-0004768

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:54:12
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '14 Aug 2020 12:00'	(b) (4), (b) (6) System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004769

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:54:12
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004770

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:54:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
Data entry locked.	System	11 Aug 2020 00:33:30
User entered 'Day 6'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004771

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:54:12
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-15T18:44:25', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '227a1230-d60f-4950-b462-35b2242969f2'	System	15 Aug 2020 23:45:07
User entered 'None (0)'	System	15 Aug 2020 23:45:07

FDA-CBER-2022-1614-0004772

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:54:12
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-15T18:44:28', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '227a1230-d60f-4950-b462-35b2242969f2'	System	15 Aug 2020 23:45:07
User entered 'None (0)'	System	15 Aug 2020 23:45:07

FDA-CBER-2022-1614-0004773

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:54:12
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-15T18:44:38', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '227a1230-d60f-4950-b462-35b2242969f2'	System	15 Aug 2020 23:45:07
User entered 'None (0)'	System	15 Aug 2020 23:45:07

FDA-CBER-2022-1614-0004774

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:54:12
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-15T18:44:42', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '227a1230-d60f-4950-b462-35b2242969f2'	System	15 Aug 2020 23:45:07
User entered 'None (0)'	System	15 Aug 2020 23:45:07

FDA-CBER-2022-1614-0004775

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:54:12
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-15T18:44:45', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '227a1230-d60f-4950-b462-35b2242969f2'	System	15 Aug 2020 23:45:07
User entered 'None (0)'	System	15 Aug 2020 23:45:07

FDA-CBER-2022-1614-0004776

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:54:12
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-15T18:44:48', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '227a1230-d60f-4950-b462-35b2242969f2'	System	15 Aug 2020 23:45:07
User entered 'None (0)'	System	15 Aug 2020 23:45:07

FDA-CBER-2022-1614-0004777

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:54:12
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) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-15T18:44:54', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '227a1230-d60f-4950-b462-35b2242969f2'	System	15 Aug 2020 23:45:07
User entered 'No (N)'	System	15 Aug 2020 23:45:07

FDA-CBER-2022-1614-0004778

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:54:12
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-15T18:45:03', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '227a1230-d60f-4950-b462-35b2242969f2'	System	15 Aug 2020 23:45:07
User entered '15 Aug 2020 18:45'	System	15 Aug 2020 23:45:07

FDA-CBER-2022-1614-0004779

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:54:12
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004780

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:54:12
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004781

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:54:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
Data entry locked.	System	11 Aug 2020 00:33:30
User entered 'Day 7'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004782

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:54:12
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-16T23:46:29', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '86dbbedc-fcb5-45d2-8fb6-1e242a582f73'	System	17 Aug 2020 04:47:05
User entered 'None (0)'	System	17 Aug 2020 04:47:05

FDA-CBER-2022-1614-0004783

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:54:12
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-16T23:46:33', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '86dbbedc-fcb5-45d2-8fb6-1e242a582f73'	System	17 Aug 2020 04:47:05
User entered 'None (0)'	System	17 Aug 2020 04:47:05

FDA-CBER-2022-1614-0004784

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:54:12
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-16T23:46:36', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '86dbbedc-fcb5-45d2-8fb6-1e242a582f73'	System	17 Aug 2020 04:47:05
User entered 'None (0)'	System	17 Aug 2020 04:47:05

FDA-CBER-2022-1614-0004785

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:54:12
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-16T23:46:40', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '86dbbedc-fcb5-45d2-8fb6-1e242a582f73'	System	17 Aug 2020 04:47:05
User entered 'None (0)'	System	17 Aug 2020 04:47:05

FDA-CBER-2022-1614-0004786

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:54:12
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-16T23:46:42', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '86dbbedc-fcb5-45d2-8fb6-1e242a582f73'	System	17 Aug 2020 04:47:05
User entered 'None (0)'	System	17 Aug 2020 04:47:05

FDA-CBER-2022-1614-0004787

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:54:12
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-16T23:46:46', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '86dbbedc-fcb5-45d2-8fb6-1e242a582f73'	System	17 Aug 2020 04:47:05
User entered 'None (0)'	System	17 Aug 2020 04:47:05

FDA-CBER-2022-1614-0004788

US3012098

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:54:12

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) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-16T23:46:50', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '86dbbedc-fcb5-45d2-8fb6-1e242a582f73'	System	17 Aug 2020 04:47:05
User entered 'No (N)'	System	17 Aug 2020 04:47:05

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:54:12
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-08-16T23:47:01', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '86dbbedc-fcb5-45d2-8fb6-1e242a582f73'	System	17 Aug 2020 04:47:05
User entered '16 Aug 2020 23:47'	System	17 Aug 2020 04:47:05

FDA-CBER-2022-1614-0004790

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:54:12
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '16 Aug 2020 12:00'	(b) (4), (b) (6) System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004791

US3012098
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:54:12
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0004792

US3012098
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:54:12
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	19 Aug 2020 14:44:27

FDA-CBER-2022-1614-0004793

US3012098
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:54:12
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '19 Aug 2020'	Tambra Dora (b) (4) (b) (4)	19 Aug 2020 14:44:27

FDA-CBER-2022-1614-0004794

US3012098
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:54:12
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Contact Made (CONTACT MADE)'	Tambra Dora (b) (4) (b) (4)	19 Aug 2020 14:44:27

US3012098
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:54:12
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	Tambra Dora (b) (4) (b) (4)	19 Aug 2020 14:44:27

FDA-CBER-2022-1614-0004796

US3012098
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:54:12
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	19 Aug 2020 14:44:32

FDA-CBER-2022-1614-0004797

US3012098
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:54:12
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '1'	(b) (4), (b) (6) System	19 Aug 2020 14:44:32

FDA-CBER-2022-1614-0004798

US3012098
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:54:12
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	Michelle Listz (b) (4) (b) (4)	26 Aug 2020 22:07:52

FDA-CBER-2022-1614-0004799

US3012098
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:54:12
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '26 Aug 2020'	Michelle Listz (b) (4) (b) (4)	26 Aug 2020 22:07:52

US3012098
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:54:12
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Contact Made (CONTACT MADE)'	Michelle Listz (b) (4) (b) (4)	26 Aug 2020 22:07:52

US3012098
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:54:12
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	Michelle Listz (b) (4) (b) (4)	26 Aug 2020 22:07:52

FDA-CBER-2022-1614-0004802

US3012098
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:54:12
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	Michelle Listz (b) (4) (b) (4)	26 Aug 2020 22:07:57

FDA-CBER-2022-1614-0004803

US3012098
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:54:12
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '1'	System	26 Aug 2020 22:07:57

FDA-CBER-2022-1614-0004804

US3012098
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:54:12
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	01 Sep 2020 17:20:44

FDA-CBER-2022-1614-0004805

US3012098
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:54:12
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '1 Sep 2020'	Tambra Dora (b) (4) (b) (4)	01 Sep 2020 17:20:44

FDA-CBER-2022-1614-0004806

US3012098
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:54:12
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Contact Made (CONTACT MADE)'	Tambra Dora (b) (4) (b) (4)	01 Sep 2020 17:20:44

US3012098
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:54:12
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	Tambra Dora (b) (4) (b) (4)	01 Sep 2020 17:20:44

FDA-CBER-2022-1614-0004808

US3012098
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:54:12
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	01 Sep 2020 17:20:50

FDA-CBER-2022-1614-0004809

US3012098
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:54:12
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '1'	System	01 Sep 2020 17:20:50

FDA-CBER-2022-1614-0004810

US3012098
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:54:12
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:13:43

US3012098
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:54:12
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '08 Sep 2020'	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:13:43

FDA-CBER-2022-1614-0004812

US3012098
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:54:12
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Clinic (Clinic)'	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:13:43

FDA-CBER-2022-1614-0004813

US3012098
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:54:12
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User entered 'VISIT2'	System	08 Sep 2020 13:13:43

FDA-CBER-2022-1614-0004814

US3012098
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:54:12
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User accepted default value 'Pre-Dose (PREDOSE)'	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:16:21

FDA-CBER-2022-1614-0004815

US3012098
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:54:12
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:16:21

FDA-CBER-2022-1614-0004816

US3012098
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:54:12
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '08 Sep 2020'	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:16:21

FDA-CBER-2022-1614-0004817

US3012098
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:54:12
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '07:23'	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:16:21

FDA-CBER-2022-1614-0004818

US3012098
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:54:12
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User entered '08 Sep 2020 07:23'	(b) (4), (b) (6) System	08 Sep 2020 13:16:21

FDA-CBER-2022-1614-0004819

US3012098
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:54:12
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '97.8' F	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:16:21

FDA-CBER-2022-1614-0004820

US3012098
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:54:12
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Oral (Oral)'	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:16:21

FDA-CBER-2022-1614-0004821

US3012098
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:54:12
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:16:21

FDA-CBER-2022-1614-0004822

US3012098
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:54:12
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '86'	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:16:21

FDA-CBER-2022-1614-0004823

US3012098
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:54:12
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User entered 'bpm'	System	08 Sep 2020 13:16:21

FDA-CBER-2022-1614-0004824

US3012098
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:54:12
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '14'	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:16:21

FDA-CBER-2022-1614-0004825

US3012098
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:54:12
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User entered 'breaths/min'	System	08 Sep 2020 13:16:21

FDA-CBER-2022-1614-0004826

US3012098
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:54:12
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '126'	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:16:21

FDA-CBER-2022-1614-0004827

US3012098
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:54:12
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User entered 'mmHg'	System	08 Sep 2020 13:16:21

FDA-CBER-2022-1614-0004828

US3012098
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:54:12
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '85'	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:16:21

FDA-CBER-2022-1614-0004829

US3012098
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 09 Jun 2021 14:54:12
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User entered 'mmHg'	System	08 Sep 2020 13:16:21

FDA-CBER-2022-1614-0004830

US3012098
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:54:12
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User accepted default value 'Post-Dose (POSTDOSE)'	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 00:35:52

FDA-CBER-2022-1614-0004831

US3012098
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:54:12
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 00:35:52

FDA-CBER-2022-1614-0004832

US3012098
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:54:12
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '08 Sep 2020'	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 00:35:52

FDA-CBER-2022-1614-0004833

US3012098
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:54:12
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '09:24'	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 00:35:52

FDA-CBER-2022-1614-0004834

US3012098
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:54:12
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User entered '08 Sep 2020 09:24'	(b) (4), (b) (6) System	09 Sep 2020 00:35:52

FDA-CBER-2022-1614-0004835

US3012098
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:54:12
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '97.7' F	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 00:35:52

FDA-CBER-2022-1614-0004836

US3012098
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:54:12
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Oral (Oral)'	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 00:35:52

FDA-CBER-2022-1614-0004837

US3012098
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:54:12
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 00:35:52

FDA-CBER-2022-1614-0004838

US3012098
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:54:12
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '80'	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 00:35:52

FDA-CBER-2022-1614-0004839

US3012098
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:54:12
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User entered 'bpm'	System	09 Sep 2020 00:35:52

FDA-CBER-2022-1614-0004840

US3012098
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:54:12
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '14'	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 00:35:52

FDA-CBER-2022-1614-0004841

US3012098
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:54:12
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User entered 'breaths/min'	System	09 Sep 2020 00:35:52

FDA-CBER-2022-1614-0004842

US3012098
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:54:12
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '119'	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 00:35:52

FDA-CBER-2022-1614-0004843

US3012098
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:54:12
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User entered 'mmHg'	System	09 Sep 2020 00:35:52

FDA-CBER-2022-1614-0004844

US3012098
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:54:12
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '83'	Jennifer Leyva (b) (4) (b) (4)	09 Sep 2020 00:35:52

FDA-CBER-2022-1614-0004845

US3012098
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 09 Jun 2021 14:54:12
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User entered 'mmHg'	System	09 Sep 2020 00:35:52

FDA-CBER-2022-1614-0004846

US3012098
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 14:54:12
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:16:36

FDA-CBER-2022-1614-0004847

US3012098
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 14:54:12
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '08 Sep 2020'	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:16:36

FDA-CBER-2022-1614-0004848

US3012098
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:54:12
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0004849

US3012098
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:54:12
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0004850

US3012098

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:54:12

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) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 14:16:24

US3012098
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:54:12
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User entered 'MRNA-1273 OR PLACEBO'	System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0004852

US3012098
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:54:12
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '08 Sep 2020'	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0004853

US3012098
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:54:12
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '08:44'	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0004854

US3012098
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:54:12
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User entered '08 Sep 2020 08:44'	System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0004855

US3012098
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:54:12
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Left Arm (LEFT ARM)'	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0004856

US3012098
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:54:12
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User entered 'ONCE'	System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0004857

US3012098
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 09 Jun 2021 14:54:12
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User entered 'INTRAMUSCULAR'	System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0004858

US3012098
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 14:54:12
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:17:00

FDA-CBER-2022-1614-0004859

US3012098
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 14:54:12
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '08 Sep 2020'	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:17:00

FDA-CBER-2022-1614-0004860

US3012098
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 14:54:12
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '07:55' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:17:08
User entered '07:23'	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:17:00

FDA-CBER-2022-1614-0004861

US3012098
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 14:54:12
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User entered '08 Sep 2020 07:55'	System	08 Sep 2020 13:17:08
User entered '08 Sep 2020 07:23'	System	08 Sep 2020 13:17:00

FDA-CBER-2022-1614-0004862

US3012098
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 09 Jun 2021 14:54:12
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '08 Sep 2020'	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:17:19

FDA-CBER-2022-1614-0004863

US3012098
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 14:54:12
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:17:19

FDA-CBER-2022-1614-0004864

US3012098
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 14:54:12
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:17:19

FDA-CBER-2022-1614-0004865

US3012098
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 14:54:12
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '07:42'	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:17:19

FDA-CBER-2022-1614-0004866

US3012098
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 09 Jun 2021 14:54:12
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User entered '08 Sep 2020 07:42'	(b) (4), (b) (6) System	08 Sep 2020 13:17:19

FDA-CBER-2022-1614-0004867

US3012098
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 14:54:12
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:17:19

FDA-CBER-2022-1614-0004868

US3012098
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 14:54:12
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:17:19

FDA-CBER-2022-1614-0004869

US3012098
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 14:54:12
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:17:19

FDA-CBER-2022-1614-0004870

US3012098
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 09 Jun 2021 14:54:12
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User entered empty.	System	08 Sep 2020 13:17:19

FDA-CBER-2022-1614-0004871

US3012098
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:54:12
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:17:22

FDA-CBER-2022-1614-0004872

US3012098
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:54:12
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User entered '1'	System	08 Sep 2020 13:17:22

FDA-CBER-2022-1614-0004873

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 14:54:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
Data entry locked.	System	08 Sep 2020 14:16:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0004874

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 14:54:12
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T09:20:53', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'eed2fee6-3e65-4e3c-943e-cba6a65eb4f2'	System	08 Sep 2020 14:21:17
User entered 'Yes (Y)'	System	08 Sep 2020 14:21:17

FDA-CBER-2022-1614-0004875

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 14:54:12
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T09:21:00', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'eed2fee6-3e65-4e3c-943e-cba6a65eb4f2'	System	08 Sep 2020 14:21:17
User entered '97.7'	System	08 Sep 2020 14:21:17

FDA-CBER-2022-1614-0004876

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 14:54:12
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T09:21:06', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'eed2fee6-3e65-4e3c-943e-cba6a65eb4f2'	System	08 Sep 2020 14:21:17
User entered 'No (N)'	System	08 Sep 2020 14:21:17

FDA-CBER-2022-1614-0004877

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 14:54:12
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T09:21:12', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'eed2fee6-3e65-4e3c-943e-cba6a65eb4f2'	System	08 Sep 2020 14:21:17
User entered '08 Sep 2020 09:21'	System	08 Sep 2020 14:21:17

FDA-CBER-2022-1614-0004878

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 14:54:12
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '08 Sep 2020 09:04'	System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0004879

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 09 Jun 2021 14:54:12
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '08 Sep 2020 11:34'	(b) (4), (b) (6) System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0004880

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 14:54:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
Data entry locked.	System	08 Sep 2020 14:16:24
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0004881

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 14:54:12
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T19:45:03', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '2dd18287-40ac-4d93-9823-8260f181ef3d'	System	09 Sep 2020 00:45:31
User entered 'Yes (Y)'	System	09 Sep 2020 00:45:31

FDA-CBER-2022-1614-0004882

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 14:54:12
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T19:45:09', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '2dd18287-40ac-4d93-9823-8260f181ef3d'	System	09 Sep 2020 00:45:31
User entered '98.2'	System	09 Sep 2020 00:45:31

FDA-CBER-2022-1614-0004883

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 14:54:12
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T19:45:13', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '2dd18287-40ac-4d93-9823-8260f181ef3d'	System	09 Sep 2020 00:45:31
User entered 'No (N)'	System	09 Sep 2020 00:45:31

FDA-CBER-2022-1614-0004884

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 14:54:12
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T19:45:23', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '2dd18287-40ac-4d93-9823-8260f181ef3d'	System	09 Sep 2020 00:45:31
User entered '08 Sep 2020 19:45'	System	09 Sep 2020 00:45:31

FDA-CBER-2022-1614-0004885

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 14:54:12
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '08 Sep 2020 12:29'	System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0004886

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 09 Jun 2021 14:54:12
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '09 Sep 2020 11:59'	(b) (4), (b) (6) System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0004887

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:54:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
Data entry locked.	System	08 Sep 2020 14:16:24
User entered 'Day 2'	System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0004888

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:54:12
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-09T17:51:45', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'daf298f9-f3f0-4e5e-843a-6d44924eeb8e'	System	09 Sep 2020 22:52:12
User entered 'Yes (Y)'	System	09 Sep 2020 22:52:12

FDA-CBER-2022-1614-0004889

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:54:12
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-09T17:51:51', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'daf298f9-f3f0-4e5e-843a-6d44924eeb8e'	System	09 Sep 2020 22:52:12
User entered '98.8'	System	09 Sep 2020 22:52:12

FDA-CBER-2022-1614-0004890

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:54:12
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-09T17:52:00', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'daf298f9-f3f0-4e5e-843a-6d44924eeb8e'	System	09 Sep 2020 22:52:12
User entered 'No (N)'	System	09 Sep 2020 22:52:12

FDA-CBER-2022-1614-0004891

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:54:12
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-09T17:52:06', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'daf298f9-f3f0-4e5e-843a-6d44924eeb8e'	System	09 Sep 2020 22:52:12
User entered '09 Sep 2020 17:52'	System	09 Sep 2020 22:52:12

FDA-CBER-2022-1614-0004892

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:54:12
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0004893

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 09 Jun 2021 14:54:12
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '10 Sep 2020 11:59'	(b) (4), (b) (6) System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0004894

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:54:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
Data entry locked.	System	08 Sep 2020 14:16:24
User entered 'Day 3'	System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0004895

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:54:12
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-10T19:54:04', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'f06c3f09-f606-4d11-964d-93e6cc1fa6fc'	System	11 Sep 2020 00:54:29
User entered 'Yes (Y)'	System	11 Sep 2020 00:54:29

FDA-CBER-2022-1614-0004896

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:54:12
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-10T19:54:12', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'f06c3f09-f606-4d11-964d-93e6cc1fa6fc'	System	11 Sep 2020 00:54:29
User entered '97.1'	System	11 Sep 2020 00:54:29

FDA-CBER-2022-1614-0004897

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:54:12
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-10T19:54:17', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'f06c3f09-f606-4d11-964d-93e6cc1fa6fc'	System	11 Sep 2020 00:54:29
User entered 'No (N)'	System	11 Sep 2020 00:54:29

FDA-CBER-2022-1614-0004898

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:54:12
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-10T19:54:24', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'f06c3f09-f606-4d11-964d-93e6cc1fa6fc'	System	11 Sep 2020 00:54:29
User entered '10 Sep 2020 19:54'	System	11 Sep 2020 00:54:29

FDA-CBER-2022-1614-0004899

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:54:12
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0004900

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 09 Jun 2021 14:54:12
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '11 Sep 2020 11:59'	(b) (4), (b) (6) System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0004901

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 14:54:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
Data entry locked.	System	08 Sep 2020 14:16:24
User entered 'Day 4'	System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0004902

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 14:54:12
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-11T19:23:43', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '50c43d24-61a3-4d5e-bdf7-752594435695'	System	12 Sep 2020 00:24:08
User entered 'Yes (Y)'	System	12 Sep 2020 00:24:08

FDA-CBER-2022-1614-0004903

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 14:54:12
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-11T19:23:50', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '50c43d24-61a3-4d5e-bdf7-752594435695'	System	12 Sep 2020 00:24:08
User entered '98.6'	System	12 Sep 2020 00:24:08

FDA-CBER-2022-1614-0004904

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 14:54:12
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-11T19:23:54', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '50c43d24-61a3-4d5e-bdf7-752594435695'	System	12 Sep 2020 00:24:08
User entered 'No (N)'	System	12 Sep 2020 00:24:08

FDA-CBER-2022-1614-0004905

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 14:54:12
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-11T19:24:02', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '50c43d24-61a3-4d5e-bdf7-752594435695'	System	12 Sep 2020 00:24:08
User entered '11 Sep 2020 19:24'	System	12 Sep 2020 00:24:08

FDA-CBER-2022-1614-0004906

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 14:54:12
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '11 Sep 2020 12:00'	(b) (4), (b) (6) System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0004907

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 09 Jun 2021 14:54:12
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '12 Sep 2020 11:59'	(b) (4), (b) (6) System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0004908

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:54:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
Data entry locked.	System	08 Sep 2020 14:16:24
User entered 'Day 5'	System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0004909

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:54:12
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-12T21:21:18', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '8f1eaeb5-7b06-458a-9189-124ba143e6dd'	System	13 Sep 2020 02:21:52
User entered 'Yes (Y)'	System	13 Sep 2020 02:21:52

FDA-CBER-2022-1614-0004910

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:54:12
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-12T21:21:35', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '8f1eaeb5-7b06-458a-9189-124ba143e6dd'	System	13 Sep 2020 02:21:52
User entered '96.8'	System	13 Sep 2020 02:21:52

FDA-CBER-2022-1614-0004911

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:54:12
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-12T21:21:39', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '8f1eaeb5-7b06-458a-9189-124ba143e6dd'	System	13 Sep 2020 02:21:52
User entered 'No (N)'	System	13 Sep 2020 02:21:52

FDA-CBER-2022-1614-0004912

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:54:12
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-12T21:21:46', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '8f1eaeb5-7b06-458a-9189-124ba143e6dd'	System	13 Sep 2020 02:21:52
User entered '12 Sep 2020 21:21'	System	13 Sep 2020 02:21:52

FDA-CBER-2022-1614-0004913

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:54:12
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0004914

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 09 Jun 2021 14:54:12
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '13 Sep 2020 11:59'	(b) (4), (b) (6) System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0004915

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:54:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
Data entry locked.	System	08 Sep 2020 14:16:24
User entered 'Day 6'	System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0004916

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:54:12
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-13T17:40:08', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '1430dc28-60d1-4579-be2f-2ce4b28717ec'	System	13 Sep 2020 22:40:34
User entered 'Yes (Y)'	System	13 Sep 2020 22:40:34

FDA-CBER-2022-1614-0004917

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:54:12
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-13T17:40:19', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '1430dc28-60d1-4579-be2f-2ce4b28717ec'	System	13 Sep 2020 22:40:34
User entered '97.6'	System	13 Sep 2020 22:40:34

FDA-CBER-2022-1614-0004918

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:54:12
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-13T17:40:22', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '1430dc28-60d1-4579-be2f-2ce4b28717ec'	System	13 Sep 2020 22:40:34
User entered 'No (N)'	System	13 Sep 2020 22:40:34

FDA-CBER-2022-1614-0004919

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:54:12
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-13T17:40:29', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '1430dc28-60d1-4579-be2f-2ce4b28717ec'	System	13 Sep 2020 22:40:34
User entered '13 Sep 2020 17:40'	System	13 Sep 2020 22:40:34

FDA-CBER-2022-1614-0004920

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:54:12
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '13 Sep 2020 12:00'	(b) (4), (b) (6) System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0004921

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 09 Jun 2021 14:54:12
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '14 Sep 2020 11:59'	(b) (4), (b) (6) System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0004922

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:54:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
Data entry locked.	System	08 Sep 2020 14:16:24
User entered 'Day 7'	System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0004923

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:54:12
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13

FDA-CBER-2022-1614-0004924

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:54:12
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13

FDA-CBER-2022-1614-0004925

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:54:12
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13

FDA-CBER-2022-1614-0004926

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:54:12
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13

FDA-CBER-2022-1614-0004927

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:54:12
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13

FDA-CBER-2022-1614-0004928

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:54:12
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13

FDA-CBER-2022-1614-0004929

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:54:12
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '14 Sep 2020 12:00'	(b) (4), (b) (6) System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0004930

US3012098
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 09 Jun 2021 14:54:12
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '15 Sep 2020 11:59'	(b) (4), (b) (6) System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0004931

US3012098
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:54:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
Data entry locked.	System	08 Sep 2020 14:16:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 14:16:24

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:54:12

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T09:21:33', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '437a9a9c-604b-4c0a-92e5-6b57f69bcbd4'	System	08 Sep 2020 14:21:58
User entered 'None (1)'	System	08 Sep 2020 14:21:58

US3012098
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:54:12
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T09:21:37', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '437a9a9c-604b-4c0a-92e5-6b57f69bcbd4'	System	08 Sep 2020 14:21:58
User entered 'No (N)'	System	08 Sep 2020 14:21:58

FDA-CBER-2022-1614-0004934

US3012098
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:54:12
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T09:21:41', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '437a9a9c-604b-4c0a-92e5-6b57f69bcbd4'	System	08 Sep 2020 14:21:58
User entered 'No (N)'	System	08 Sep 2020 14:21:58

FDA-CBER-2022-1614-0004935

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:54:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T09:21:46', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '437a9a9c-604b-4c0a-92e5-6b57f69bcbd4'	System	08 Sep 2020 14:21:58
User entered 'None (1)'	System	08 Sep 2020 14:21:58

US3012098
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:54:12
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T09:21:53', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '437a9a9c-604b-4c0a-92e5-6b57f69bcbd4'	System	08 Sep 2020 14:21:58
User entered '08 Sep 2020 09:21'	System	08 Sep 2020 14:21:58

FDA-CBER-2022-1614-0004937

US3012098
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:54:12
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '08 Sep 2020 09:04'	(b) (4), (b) (6) System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0004938

US3012098
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 09 Jun 2021 14:54:12
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '08 Sep 2020 11:34'	System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0004939

US3012098
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:54:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
Data entry locked.	System	08 Sep 2020 14:16:24
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0004940

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:54:12

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T19:45:36', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'f771431f-7d31-42d8-9682-e28d2623e32a'	System	09 Sep 2020 00:46:24
User entered 'Does not interfere with activity (2)'	System	09 Sep 2020 00:46:24

US3012098
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:54:12
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T19:45:53', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'f771431f-7d31-42d8-9682-e28d2623e32a'	System	09 Sep 2020 00:46:24
User entered 'No (N)'	System	09 Sep 2020 00:46:24

FDA-CBER-2022-1614-0004942

US3012098
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:54:12
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T19:46:01', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'f771431f-7d31-42d8-9682-e28d2623e32a'	System	09 Sep 2020 00:46:24
User entered 'No (N)'	System	09 Sep 2020 00:46:24

FDA-CBER-2022-1614-0004943

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:54:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T19:46:06', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'f771431f-7d31-42d8-9682-e28d2623e32a'	System	09 Sep 2020 00:46:24
User entered 'None (1)'	System	09 Sep 2020 00:46:24

US3012098
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:54:12
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T19:46:14', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'f771431f-7d31-42d8-9682-e28d2623e32a'	System	09 Sep 2020 00:46:24
User entered '08 Sep 2020 19:46'	System	09 Sep 2020 00:46:24

US3012098
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:54:12
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '08 Sep 2020 12:29'	System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0004946

US3012098
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 09 Jun 2021 14:54:12
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0004947

US3012098
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:54:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
Data entry locked.	System	08 Sep 2020 14:16:24
User entered 'Day 2'	System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0004948

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:54:12

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-09T17:52:17', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'd2b101a2-2bd4-4917-8f13-c9d1ea22634d'	System	09 Sep 2020 22:55:30
User entered 'Does not interfere with activity (2)'	System	09 Sep 2020 22:55:30

US3012098
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:54:12
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-09T17:52:21', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'd2b101a2-2bd4-4917-8f13-c9d1ea22634d'	System	09 Sep 2020 22:55:30
User entered 'No (N)'	System	09 Sep 2020 22:55:30

FDA-CBER-2022-1614-0004950

US3012098
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:54:12
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-09T17:55:02', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'd2b101a2-2bd4-4917-8f13-c9d1ea22634d'	System	09 Sep 2020 22:55:30
User entered 'Yes (Y)'	System	09 Sep 2020 22:55:30

FDA-CBER-2022-1614-0004951

US3012098
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:54:12
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-09T17:55:00', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'd2b101a2-2bd4-4917-8f13-c9d1ea22634d'	System	09 Sep 2020 22:55:30
User entered '30'	System	09 Sep 2020 22:55:30

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:54:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-09T17:55:07', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'd2b101a2-2bd4-4917-8f13-c9d1ea22634d'	System	09 Sep 2020 22:55:30
User entered 'None (1)'	System	09 Sep 2020 22:55:30

US3012098
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:54:12
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-09T17:55:24', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'd2b101a2-2bd4-4917-8f13-c9d1ea22634d'	System	09 Sep 2020 22:55:30
User entered '09 Sep 2020 17:55'	System	09 Sep 2020 22:55:30

FDA-CBER-2022-1614-0004954

US3012098
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:54:12
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0004955

US3012098
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 09 Jun 2021 14:54:12
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '10 Sep 2020 11:59'	(b) (4), (b) (6) System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0004956

US3012098
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 14:54:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
Data entry locked.	System	08 Sep 2020 14:16:24
User entered 'Day 3'	System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0004957

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:54:12

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-10T19:54:33', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'b47d6b42-7e96-4aca-8aaf-f2efb0004445'	System	11 Sep 2020 00:55:05
User entered 'None (1)'	System	11 Sep 2020 00:55:05

US3012098
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 14:54:12
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-10T19:54:42', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'b47d6b42-7e96-4aca-8aaf-f2efb0004445'	System	11 Sep 2020 00:55:05
User entered 'No (N)'	System	11 Sep 2020 00:55:05

FDA-CBER-2022-1614-0004959

US3012098
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 14:54:12
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-10T19:54:46', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'b47d6b42-7e96-4aca-8aaf-f2efb0004445'	System	11 Sep 2020 00:55:05
User entered 'No (N)'	System	11 Sep 2020 00:55:05

FDA-CBER-2022-1614-0004960

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:54:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-10T19:54:51', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'b47d6b42-7e96-4aca-8aaf-f2efb0004445'	System	11 Sep 2020 00:55:05
User entered 'None (1)'	System	11 Sep 2020 00:55:05

US3012098
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 14:54:12
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-10T19:55:00', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'b47d6b42-7e96-4aca-8aaf-f2efb0004445'	System	11 Sep 2020 00:55:05
User entered '10 Sep 2020 19:55'	System	11 Sep 2020 00:55:05

FDA-CBER-2022-1614-0004962

US3012098
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 14:54:12
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '10 Sep 2020 12:00'	(b) (4), (b) (6) System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0004963

US3012098
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 09 Jun 2021 14:54:12
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0004964

US3012098
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:54:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
Data entry locked.	System	08 Sep 2020 14:16:24
User entered 'Day 4'	System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0004965

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:54:12

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-11T19:24:08', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'f1915666-c53d-4bfc-9c3f-50cbf2f31158'	System	12 Sep 2020 00:24:33
User entered 'None (1)'	System	12 Sep 2020 00:24:33

US3012098
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:54:12
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-11T19:24:12', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'f1915666-c53d-4bfc-9c3f-50cbf2f31158'	System	12 Sep 2020 00:24:33
User entered 'No (N)'	System	12 Sep 2020 00:24:33

FDA-CBER-2022-1614-0004967

US3012098
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:54:12
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-11T19:24:16', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'f1915666-c53d-4bfc-9c3f-50cbf2f31158'	System	12 Sep 2020 00:24:33
User entered 'No (N)'	System	12 Sep 2020 00:24:33

FDA-CBER-2022-1614-0004968

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:54:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-11T19:24:21', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'f1915666-c53d-4bfc-9c3f-50cbf2f31158'	System	12 Sep 2020 00:24:33
User entered 'None (1)'	System	12 Sep 2020 00:24:33

US3012098
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:54:12
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-11T19:24:28', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'f1915666-c53d-4bfc-9c3f-50cbf2f31158'	System	12 Sep 2020 00:24:33
User entered '11 Sep 2020 19:24'	System	12 Sep 2020 00:24:33

FDA-CBER-2022-1614-0004970

US3012098
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:54:12
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '11 Sep 2020 12:00'	(b) (4), (b) (6) System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0004971

US3012098
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 09 Jun 2021 14:54:12
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '12 Sep 2020 11:59'	(b) (4), (b) (6) System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0004972

US3012098
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:54:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
Data entry locked.	System	08 Sep 2020 14:16:24
User entered 'Day 5'	System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0004973

US3012098
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:54:12
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-12T21:21:54', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '45df198c-afc9-4695-adaf-4e31d09b6cdd'	System	13 Sep 2020 02:22:29
User entered 'None (1)'	System	13 Sep 2020 02:22:29

FDA-CBER-2022-1614-0004974

US3012098
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:54:12
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-12T21:21:59', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '45df198c-afc9-4695-adaf-4e31d09b6cdd'	System	13 Sep 2020 02:22:29
User entered 'No (N)'	System	13 Sep 2020 02:22:29

FDA-CBER-2022-1614-0004975

US3012098
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:54:12
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-12T21:22:05', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '45df198c-afc9-4695-adaf-4e31d09b6cdd'	System	13 Sep 2020 02:22:29
User entered 'No (N)'	System	13 Sep 2020 02:22:29

FDA-CBER-2022-1614-0004976

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:54:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-12T21:22:09', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '45df198c-afc9-4695-adaf-4e31d09b6cdd'	System	13 Sep 2020 02:22:29
User entered 'None (1)'	System	13 Sep 2020 02:22:29

US3012098
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:54:12
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-12T21:22:21', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '45df198c-afc9-4695-adaf-4e31d09b6cdd'	System	13 Sep 2020 02:22:29
User entered '12 Sep 2020 21:22'	System	13 Sep 2020 02:22:29

FDA-CBER-2022-1614-0004978

US3012098
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:54:12
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0004979

US3012098
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 09 Jun 2021 14:54:12
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '13 Sep 2020 11:59'	(b) (4), (b) (6) System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0004980

US3012098
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:54:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
Data entry locked.	System	08 Sep 2020 14:16:24
User entered 'Day 6'	System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0004981

US3012098
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:54:12
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-13T17:40:36', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '4815a2dd-5bc5-4588-936e-51dae2f81cff'	System	13 Sep 2020 22:41:00
User entered 'None (1)'	System	13 Sep 2020 22:41:00

FDA-CBER-2022-1614-0004982

US3012098
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:54:12
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-13T17:40:40', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '4815a2dd-5bc5-4588-936e-51dae2f81cff'	System	13 Sep 2020 22:41:00
User entered 'No (N)'	System	13 Sep 2020 22:41:00

FDA-CBER-2022-1614-0004983

US3012098
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:54:12
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-13T17:40:43', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '4815a2dd-5bc5-4588-936e-51dae2f81cff'	System	13 Sep 2020 22:41:00
User entered 'No (N)'	System	13 Sep 2020 22:41:00

FDA-CBER-2022-1614-0004984

US3012098

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:54:12

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-13T17:40:48', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '4815a2dd-5bc5-4588-936e-51dae2f81cff'	System	13 Sep 2020 22:41:00
User entered 'None (1)'	System	13 Sep 2020 22:41:00

US3012098
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:54:12
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-13T17:40:54', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '4815a2dd-5bc5-4588-936e-51dae2f81cff'	System	13 Sep 2020 22:41:00
User entered '13 Sep 2020 17:40'	System	13 Sep 2020 22:41:00

FDA-CBER-2022-1614-0004986

US3012098
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:54:12
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 14:16:24

US3012098
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 09 Jun 2021 14:54:12
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '14 Sep 2020 11:59'	(b) (4), (b) (6) System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0004988

US3012098
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:54:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
Data entry locked.	System	08 Sep 2020 14:16:24
User entered 'Day 7'	System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0004989

US3012098
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:54:12
Please record - **PAIN AT INJECTION SITE.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13

FDA-CBER-2022-1614-0004990

US3012098
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:54:12
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13

FDA-CBER-2022-1614-0004991

US3012098
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:54:12
Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13

FDA-CBER-2022-1614-0004992

US3012098
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:54:12
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13

FDA-CBER-2022-1614-0004993

US3012098
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:54:12
Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13

FDA-CBER-2022-1614-0004994

US3012098
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:54:12
Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**
Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13

FDA-CBER-2022-1614-0004995

US3012098
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:54:12
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13

FDA-CBER-2022-1614-0004996

US3012098
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:54:12
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '14 Sep 2020 12:00'	(b) (4), (b) (6) System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0004997

US3012098
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 09 Jun 2021 14:54:12
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0004998

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:54:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
Data entry locked.	System	08 Sep 2020 14:16:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0004999

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:54:12
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T09:21:59', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'd8202aa7-3169-47fd-8910-e13da79fb085'	System	08 Sep 2020 14:22:34
User entered 'None (0)'	System	08 Sep 2020 14:22:34

FDA-CBER-2022-1614-0005000

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:54:12
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T09:22:02', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'd8202aa7-3169-47fd-8910-e13da79fb085'	System	08 Sep 2020 14:22:34
User entered 'None (0)'	System	08 Sep 2020 14:22:34

FDA-CBER-2022-1614-0005001

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:54:12
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T09:22:05', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'd8202aa7-3169-47fd-8910-e13da79fb085'	System	08 Sep 2020 14:22:34
User entered 'None (0)'	System	08 Sep 2020 14:22:34

FDA-CBER-2022-1614-0005002

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:54:12
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T09:22:09', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'd8202aa7-3169-47fd-8910-e13da79fb085'	System	08 Sep 2020 14:22:34
User entered 'None (0)'	System	08 Sep 2020 14:22:34

FDA-CBER-2022-1614-0005003

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:54:12
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T09:22:16', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'd8202aa7-3169-47fd-8910-e13da79fb085'	System	08 Sep 2020 14:22:34
User entered 'None (0)'	System	08 Sep 2020 14:22:34

FDA-CBER-2022-1614-0005004

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:54:12
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T09:22:18', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'd8202aa7-3169-47fd-8910-e13da79fb085'	System	08 Sep 2020 14:22:34
User entered 'None (0)'	System	08 Sep 2020 14:22:34

FDA-CBER-2022-1614-0005005

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:54:12
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) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T09:22:22', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'd8202aa7-3169-47fd-8910-e13da79fb085'	System	08 Sep 2020 14:22:34
User entered 'No (N)'	System	08 Sep 2020 14:22:34

FDA-CBER-2022-1614-0005006

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:54:12
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T09:22:25', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'd8202aa7-3169-47fd-8910-e13da79fb085'	System	08 Sep 2020 14:22:34
User entered '08 Sep 2020 09:22'	System	08 Sep 2020 14:22:34

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:54:12
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '08 Sep 2020 09:04'	System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0005008

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 09 Jun 2021 14:54:12
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '08 Sep 2020 11:34'	System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0005009

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:54:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
Data entry locked.	System	08 Sep 2020 14:16:24
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 14:16:24

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:54:12
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T19:46:21', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '69b0d55e-11a7-4f77-be86-cad6340cbe65'	System	09 Sep 2020 00:47:09
User entered 'None (0)'	System	09 Sep 2020 00:47:09

FDA-CBER-2022-1614-0005011

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:54:12
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T19:46:30', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '69b0d55e-11a7-4f77-be86-cad6340cbe65'	System	09 Sep 2020 00:47:09
User entered 'No interference with activity (1)'	System	09 Sep 2020 00:47:09

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:54:12
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T19:46:34', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '69b0d55e-11a7-4f77-be86-cad6340cbe65'	System	09 Sep 2020 00:47:09
User entered 'None (0)'	System	09 Sep 2020 00:47:09

FDA-CBER-2022-1614-0005013

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:54:12
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T19:46:39', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '69b0d55e-11a7-4f77-be86-cad6340cbe65'	System	09 Sep 2020 00:47:09
User entered 'None (0)'	System	09 Sep 2020 00:47:09

FDA-CBER-2022-1614-0005014

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:54:12
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T19:46:42', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '69b0d55e-11a7-4f77-be86-cad6340cbe65'	System	09 Sep 2020 00:47:09
User entered 'None (0)'	System	09 Sep 2020 00:47:09

FDA-CBER-2022-1614-0005015

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:54:12
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T19:46:45', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '69b0d55e-11a7-4f77-be86-cad6340cbe65'	System	09 Sep 2020 00:47:09
User entered 'None (0)'	System	09 Sep 2020 00:47:09

FDA-CBER-2022-1614-0005016

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:54:12
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) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T19:46:49', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '69b0d55e-11a7-4f77-be86-cad6340cbe65'	System	09 Sep 2020 00:47:09
User entered 'No (N)'	System	09 Sep 2020 00:47:09

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:54:12
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-08T19:47:01', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '69b0d55e-11a7-4f77-be86-cad6340cbe65'	System	09 Sep 2020 00:47:09
User entered '08 Sep 2020 19:47'	System	09 Sep 2020 00:47:09

FDA-CBER-2022-1614-0005018

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:54:12
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '08 Sep 2020 12:29'	System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0005019

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 09 Jun 2021 14:54:12
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0005020

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:54:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
Data entry locked.	System	08 Sep 2020 14:16:24
User entered 'Day 2'	System	08 Sep 2020 14:16:24

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:54:12
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-09T17:55:34', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '370790e5-3960-4410-bc9a-3cdf525fc7f1'	System	09 Sep 2020 22:56:18
User entered 'No interference with activity (1)'	System	09 Sep 2020 22:56:18

FDA-CBER-2022-1614-0005022

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:54:12
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-09T17:55:39', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '370790e5-3960-4410-bc9a-3cdf525fc7f1'	System	09 Sep 2020 22:56:18
User entered 'No interference with activity (1)'	System	09 Sep 2020 22:56:18

FDA-CBER-2022-1614-0005023

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:54:12
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-09T17:55:47', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '370790e5-3960-4410-bc9a-3cdf525fc7f1'	System	09 Sep 2020 22:56:18
User entered 'No interference with activity (1)'	System	09 Sep 2020 22:56:18

FDA-CBER-2022-1614-0005024

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:54:12
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-09T17:55:51', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '370790e5-3960-4410-bc9a-3cdf525fc7f1'	System	09 Sep 2020 22:56:18
User entered 'No interference with activity (1)'	System	09 Sep 2020 22:56:18

FDA-CBER-2022-1614-0005025

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:54:12
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-09T17:55:55', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '370790e5-3960-4410-bc9a-3cdf525fc7f1'	System	09 Sep 2020 22:56:18
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	09 Sep 2020 22:56:18

FDA-CBER-2022-1614-0005026

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:54:12
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-09T17:55:59', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '370790e5-3960-4410-bc9a-3cdf525fc7f1'	System	09 Sep 2020 22:56:18
User entered 'No interference with activity (1)'	System	09 Sep 2020 22:56:18

FDA-CBER-2022-1614-0005027

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:54:12
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) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-09T17:56:02', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '370790e5-3960-4410-bc9a-3cdf525fc7f1'	System	09 Sep 2020 22:56:18
User entered 'No (N)'	System	09 Sep 2020 22:56:18

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:54:12
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-09T17:56:11', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '370790e5-3960-4410-bc9a-3cdf525fc7f1'	System	09 Sep 2020 22:56:18
User entered '09 Sep 2020 17:56'	System	09 Sep 2020 22:56:18

FDA-CBER-2022-1614-0005029

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:54:12
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0005030

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 09 Jun 2021 14:54:12
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '10 Sep 2020 11:59'	(b) (4), (b) (6) System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0005031

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:54:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
Data entry locked.	System	08 Sep 2020 14:16:24
User entered 'Day 3'	System	08 Sep 2020 14:16:24

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:54:12
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-10T19:55:07', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '01af971d-e1a2-4233-8f9b-dcf62d235b84'	System	11 Sep 2020 00:55:43
User entered 'None (0)'	System	11 Sep 2020 00:55:43

FDA-CBER-2022-1614-0005033

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:54:12
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-10T19:55:13', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '01af971d-e1a2-4233-8f9b-dcf62d235b84'	System	11 Sep 2020 00:55:43
User entered 'None (0)'	System	11 Sep 2020 00:55:43

FDA-CBER-2022-1614-0005034

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:54:12
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-10T19:55:16', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '01af971d-e1a2-4233-8f9b-dcf62d235b84'	System	11 Sep 2020 00:55:43
User entered 'None (0)'	System	11 Sep 2020 00:55:43

FDA-CBER-2022-1614-0005035

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:54:12
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-10T19:55:20', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '01af971d-e1a2-4233-8f9b-dcf62d235b84'	System	11 Sep 2020 00:55:43
User entered 'None (0)'	System	11 Sep 2020 00:55:43

FDA-CBER-2022-1614-0005036

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:54:12
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-10T19:55:23', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '01af971d-e1a2-4233-8f9b-dcf62d235b84'	System	11 Sep 2020 00:55:43
User entered 'None (0)'	System	11 Sep 2020 00:55:43

FDA-CBER-2022-1614-0005037

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:54:12
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-10T19:55:26', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '01af971d-e1a2-4233-8f9b-dcf62d235b84'	System	11 Sep 2020 00:55:43
User entered 'None (0)'	System	11 Sep 2020 00:55:43

FDA-CBER-2022-1614-0005038

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:54:12

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) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-10T19:55:29', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '01af971d-e1a2-4233-8f9b-dcf62d235b84'	System	11 Sep 2020 00:55:43
User entered 'No (N)'	System	11 Sep 2020 00:55:43

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:54:12
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-10T19:55:37', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '01af971d-e1a2-4233-8f9b-dcf62d235b84'	System	11 Sep 2020 00:55:43
User entered '10 Sep 2020 19:55'	System	11 Sep 2020 00:55:43

FDA-CBER-2022-1614-0005040

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:54:12
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0005041

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 09 Jun 2021 14:54:12
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '11 Sep 2020 11:59'	(b) (4), (b) (6) System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0005042

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:54:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
Data entry locked.	System	08 Sep 2020 14:16:24
User entered 'Day 4'	System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0005043

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:54:12
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-11T19:24:36', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'f6cf1816-0b0f-4559-99b9-2688a7d2e4f2'	System	12 Sep 2020 00:25:05
User entered 'None (0)'	System	12 Sep 2020 00:25:05

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:54:12
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-11T19:24:41', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'f6cf1816-0b0f-4559-99b9-2688a7d2e4f2'	System	12 Sep 2020 00:25:05
User entered 'None (0)'	System	12 Sep 2020 00:25:05

FDA-CBER-2022-1614-0005045

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:54:12
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-11T19:24:44', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'f6cf1816-0b0f-4559-99b9-2688a7d2e4f2'	System	12 Sep 2020 00:25:05
User entered 'None (0)'	System	12 Sep 2020 00:25:05

FDA-CBER-2022-1614-0005046

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:54:12
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-11T19:24:47', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'f6cf1816-0b0f-4559-99b9-2688a7d2e4f2'	System	12 Sep 2020 00:25:05
User entered 'None (0)'	System	12 Sep 2020 00:25:05

FDA-CBER-2022-1614-0005047

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:54:12
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-11T19:24:50', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'f6cf1816-0b0f-4559-99b9-2688a7d2e4f2'	System	12 Sep 2020 00:25:05
User entered 'None (0)'	System	12 Sep 2020 00:25:05

FDA-CBER-2022-1614-0005048

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:54:12
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-11T19:24:53', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'f6cf1816-0b0f-4559-99b9-2688a7d2e4f2'	System	12 Sep 2020 00:25:05
User entered 'None (0)'	System	12 Sep 2020 00:25:05

FDA-CBER-2022-1614-0005049

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:54:12

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) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-11T19:24:56', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'f6cf1816-0b0f-4559-99b9-2688a7d2e4f2'	System	12 Sep 2020 00:25:05
User entered 'No (N)'	System	12 Sep 2020 00:25:05

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:54:12
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-11T19:25:01', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'f6cf1816-0b0f-4559-99b9-2688a7d2e4f2'	System	12 Sep 2020 00:25:05
User entered '11 Sep 2020 19:25'	System	12 Sep 2020 00:25:05

FDA-CBER-2022-1614-0005051

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:54:12
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '11 Sep 2020 12:00'	(b) (4), (b) (6) System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0005052

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 09 Jun 2021 14:54:12
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '12 Sep 2020 11:59'	(b) (4), (b) (6) System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0005053

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:54:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
Data entry locked.	System	08 Sep 2020 14:16:24
User entered 'Day 5'	System	08 Sep 2020 14:16:24

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:54:12
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-12T21:22:41', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '2fafaedd-a17c-4e63-ac8f-d5b174477ac2'	System	13 Sep 2020 02:23:39
User entered 'None (0)'	System	13 Sep 2020 02:23:39

FDA-CBER-2022-1614-0005055

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:54:12
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-12T21:22:46', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '2fafaedd-a17c-4e63-ac8f-d5b174477ac2'	System	13 Sep 2020 02:23:39
User entered 'None (0)'	System	13 Sep 2020 02:23:39

FDA-CBER-2022-1614-0005056

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:54:12
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-12T21:22:51', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '2fafaedd-a17c-4e63-ac8f-d5b174477ac2'	System	13 Sep 2020 02:23:39
User entered 'None (0)'	System	13 Sep 2020 02:23:39

FDA-CBER-2022-1614-0005057

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:54:12
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-12T21:22:55', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '2fafaedd-a17c-4e63-ac8f-d5b174477ac2'	System	13 Sep 2020 02:23:39
User entered 'None (0)'	System	13 Sep 2020 02:23:39

FDA-CBER-2022-1614-0005058

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:54:12
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-12T21:22:59', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '2fafaedd-a17c-4e63-ac8f-d5b174477ac2'	System	13 Sep 2020 02:23:39
User entered 'None (0)'	System	13 Sep 2020 02:23:39

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:54:12
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-12T21:23:07', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '2fafaedd-a17c-4e63-ac8f-d5b174477ac2'	System	13 Sep 2020 02:23:39
User entered 'None (0)'	System	13 Sep 2020 02:23:39

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:54:12
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) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-12T21:23:21', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '2fafaedd-a17c-4e63-ac8f-d5b174477ac2'	System	13 Sep 2020 02:23:39
User entered 'No (N)'	System	13 Sep 2020 02:23:39

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:54:12
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-12T21:23:33', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '2fafaedd-a17c-4e63-ac8f-d5b174477ac2'	System	13 Sep 2020 02:23:39
User entered '12 Sep 2020 21:23'	System	13 Sep 2020 02:23:39

FDA-CBER-2022-1614-0005062

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:54:12
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0005063

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 09 Jun 2021 14:54:12
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0005064

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:54:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
Data entry locked.	System	08 Sep 2020 14:16:24
User entered 'Day 6'	System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0005065

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:54:12
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-13T17:41:01', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '0550fdbd-d866-4760-836b-456b6c7322d0'	System	13 Sep 2020 22:41:36
User entered 'None (0)'	System	13 Sep 2020 22:41:36

FDA-CBER-2022-1614-0005066

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:54:12
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-13T17:41:05', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '0550fdbd-d866-4760-836b-456b6c7322d0'	System	13 Sep 2020 22:41:36
User entered 'None (0)'	System	13 Sep 2020 22:41:36

FDA-CBER-2022-1614-0005067

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:54:12
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-13T17:41:09', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '0550fdbd-d866-4760-836b-456b6c7322d0'	System	13 Sep 2020 22:41:36
User entered 'None (0)'	System	13 Sep 2020 22:41:36

FDA-CBER-2022-1614-0005068

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:54:12
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-13T17:41:12', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '0550fdbd-d866-4760-836b-456b6c7322d0'	System	13 Sep 2020 22:41:36
User entered 'None (0)'	System	13 Sep 2020 22:41:36

FDA-CBER-2022-1614-0005069

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:54:12
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-13T17:41:15', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '0550fdbd-d866-4760-836b-456b6c7322d0'	System	13 Sep 2020 22:41:36
User entered 'None (0)'	System	13 Sep 2020 22:41:36

FDA-CBER-2022-1614-0005070

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:54:12
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-13T17:41:17', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '0550fdbd-d866-4760-836b-456b6c7322d0'	System	13 Sep 2020 22:41:36
User entered 'None (0)'	System	13 Sep 2020 22:41:36

FDA-CBER-2022-1614-0005071

US3012098

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:54:12

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) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-13T17:41:22', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '0550fdbd-d866-4760-836b-456b6c7322d0'	System	13 Sep 2020 22:41:36
User entered 'No (N)'	System	13 Sep 2020 22:41:36

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:54:12
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-09-13T17:41:30', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '0550fdbd-d866-4760-836b-456b6c7322d0'	System	13 Sep 2020 22:41:36
User entered '13 Sep 2020 17:41'	System	13 Sep 2020 22:41:36

FDA-CBER-2022-1614-0005073

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:54:12
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0005074

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 09 Jun 2021 14:54:12
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '14 Sep 2020 11:59'	(b) (4), (b) (6) System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0005075

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:54:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
Data entry locked.	System	08 Sep 2020 14:16:24
User entered 'Day 7'	System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0005076

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:54:12
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13

FDA-CBER-2022-1614-0005077

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:54:12
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13

FDA-CBER-2022-1614-0005078

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:54:12
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13

FDA-CBER-2022-1614-0005079

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:54:12
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13

FDA-CBER-2022-1614-0005080

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:54:12
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13

FDA-CBER-2022-1614-0005081

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:54:12
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13

FDA-CBER-2022-1614-0005082

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:54:12
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) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13

FDA-CBER-2022-1614-0005083

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:54:12
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13

FDA-CBER-2022-1614-0005084

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:54:12
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '14 Sep 2020 12:00'	(b) (4), (b) (6) System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0005085

US3012098
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 09 Jun 2021 14:54:12
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
User entered '15 Sep 2020 11:59'	(b) (4), (b) (6) System	08 Sep 2020 14:16:24

FDA-CBER-2022-1614-0005086

US3012098
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:54:12
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	17 Sep 2020 21:12:01

FDA-CBER-2022-1614-0005087

US3012098
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:54:12
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '17 Sep 2020'	Tambra Dora (b) (4) (b) (4)	17 Sep 2020 21:12:01

US3012098
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:54:12
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Contact Made (CONTACT MADE)'	Tambra Dora (b) (4) (b) (4)	17 Sep 2020 21:12:01

US3012098
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:54:12
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	Tambra Dora (b) (4) (b) (4)	17 Sep 2020 21:12:01

US3012098
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:54:12
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	17 Sep 2020 21:12:05

FDA-CBER-2022-1614-0005091

US3012098
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:54:12
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '1'	(b) (4), (b) (6) System	17 Sep 2020 21:12:05

FDA-CBER-2022-1614-0005092

US3012098
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:54:12
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	23 Sep 2020 15:48:54

FDA-CBER-2022-1614-0005093

US3012098
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:54:12
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '23 Sep 2020'	Tambra Dora (b) (4) (b) (4)	23 Sep 2020 15:48:54

US3012098
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:54:12
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Contact Made (CONTACT MADE)'	Tambra Dora (b) (4) (b) (4)	23 Sep 2020 15:48:54

FDA-CBER-2022-1614-0005095

US3012098
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:54:12
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	Tambra Dora (b) (4) (b) (4)	23 Sep 2020 15:48:54

FDA-CBER-2022-1614-0005096

US3012098
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:54:12
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	23 Sep 2020 15:48:58

FDA-CBER-2022-1614-0005097

US3012098
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:54:12
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '1'	System	23 Sep 2020 15:48:58

FDA-CBER-2022-1614-0005098

US3012098
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:54:12
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	01 Oct 2020 21:34:35

FDA-CBER-2022-1614-0005099

US3012098
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:54:12
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '1 Oct 2020'	Tambra Dora (b) (4) (b) (4)	01 Oct 2020 21:34:35

US3012098
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:54:12
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Contact Made (CONTACT MADE)'	Tambra Dora (b) (4) (b) (4)	01 Oct 2020 21:34:35

US3012098
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:54:12
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	Tambra Dora (b) (4) (b) (4)	01 Oct 2020 21:34:35

FDA-CBER-2022-1614-0005102

US3012098
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:54:12
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	Tambra Dora (b) (4) (b) (4)	01 Oct 2020 21:34:38

FDA-CBER-2022-1614-0005103

US3012098
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:54:12
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '1'	System	01 Oct 2020 21:34:38

FDA-CBER-2022-1614-0005104

US3012098
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:54:12
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:39:28

FDA-CBER-2022-1614-0005105

US3012098
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:54:12
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '13 Oct 2020'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:39:28

FDA-CBER-2022-1614-0005106

US3012098
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:54:12
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Clinic (Clinic)'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:39:28

US3012098
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 09 Jun 2021 14:54:12
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User entered 'VISIT3'	System	13 Oct 2020 21:39:28

FDA-CBER-2022-1614-0005108

US3012098
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:54:12
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:40:02

FDA-CBER-2022-1614-0005109

US3012098
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:54:12
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '13 Oct 2020'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:40:02

FDA-CBER-2022-1614-0005110

US3012098
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:54:12
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '15:15'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:40:02

FDA-CBER-2022-1614-0005111

US3012098
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:54:12
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User entered '13 Oct 2020 15:15'	(b) (4), (b) (6) System	13 Oct 2020 21:40:02

US3012098
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:54:12
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '98.0' F	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:40:02

FDA-CBER-2022-1614-0005113

US3012098
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:54:12
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Oral (Oral)'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:40:02

FDA-CBER-2022-1614-0005114

US3012098
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:54:12
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:40:02

US3012098
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:54:12
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '98'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:40:02

FDA-CBER-2022-1614-0005116

US3012098
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:54:12
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User entered 'bpm'	System	13 Oct 2020 21:40:02

FDA-CBER-2022-1614-0005117

US3012098
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:54:12
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '16'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:40:02

US3012098
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:54:12
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User entered 'breaths/min'	System	13 Oct 2020 21:40:02

FDA-CBER-2022-1614-0005119

US3012098
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:54:12
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '111'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:40:02

FDA-CBER-2022-1614-0005120

US3012098
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:54:12
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User entered 'mmHg'	(b) (4), (b) (6) System	13 Oct 2020 21:40:02

FDA-CBER-2022-1614-0005121

US3012098
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:54:12
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '67'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:40:02

FDA-CBER-2022-1614-0005122

US3012098
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:54:12
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User entered 'mmHg'	System	13 Oct 2020 21:40:02

FDA-CBER-2022-1614-0005123

US3012098
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:54:12
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11

FDA-CBER-2022-1614-0005124

US3012098
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 09 Jun 2021 14:54:12
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11

FDA-CBER-2022-1614-0005125

US3012098
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 14:54:12
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:40:25

FDA-CBER-2022-1614-0005126

US3012098
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 09 Jun 2021 14:54:12
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '13 Oct 2020'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:40:25

FDA-CBER-2022-1614-0005127

US3012098
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 14:54:12
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:40:42

FDA-CBER-2022-1614-0005128

US3012098
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 14:54:12
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '13 Oct 2020'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:40:42

FDA-CBER-2022-1614-0005129

US3012098
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 14:54:12
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '16:00'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:40:42

FDA-CBER-2022-1614-0005130

US3012098
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 09 Jun 2021 14:54:12
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User entered '13 Oct 2020 16:00'	(b) (4), (b) (6) System	13 Oct 2020 21:40:42

FDA-CBER-2022-1614-0005131

US3012098
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:54:12
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:40:59

FDA-CBER-2022-1614-0005132

US3012098
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:54:12
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:11
User entered '1'	(b) (4), (b) (6) System	13 Oct 2020 21:40:59

FDA-CBER-2022-1614-0005133

US3012098
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
Data entry locked.	System	11 Aug 2020 00:33:30
User entered 'Day 64'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0005134

US3012098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:12

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) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-10-14T18:08:49', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '9f69e4cb-b532-462d-a168-af45ee13d9b2'	System	14 Oct 2020 23:09:15
User entered 'No (N)'	System	14 Oct 2020 23:09:15

US3012098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:12

Have you been exposed to someone with 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) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-10-14T18:08:55', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '9f69e4cb-b532-462d-a168-af45ee13d9b2'	System	14 Oct 2020 23:09:15
User entered 'No (N)'	System	14 Oct 2020 23:09:15

US3012098
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-10-14T18:09:07', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '9f69e4cb-b532-462d-a168-af45ee13d9b2'	System	14 Oct 2020 23:09:15
User entered '14 Oct 2020 18:09:07'	System	14 Oct 2020 23:09:15

US3012098
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
Data entry locked.	System	11 Aug 2020 00:33:30
User entered '10 Oct 2020 00:01'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0005138

US3012098
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
Data entry locked.	System	11 Aug 2020 00:33:30
User entered '14 Oct 2020 23:59'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0005139

US3012098
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
Data entry locked.	System	11 Aug 2020 00:33:30
User entered 'Day 71'	System	11 Aug 2020 00:33:30

US3012098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:12

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) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-10-17T02:45:07', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '3ffef26c-5588-4092-ae38-6c1d99b736d7'	System	17 Oct 2020 07:45:22
User entered 'No (N)'	System	17 Oct 2020 07:45:22

US3012098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:12

Have you been exposed to someone with 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) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-10-17T02:45:12', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '3ffef26c-5588-4092-ae38-6c1d99b736d7'	System	17 Oct 2020 07:45:22
User entered 'No (N)'	System	17 Oct 2020 07:45:22

US3012098
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-10-17T02:45:18', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '3ffef26c-5588-4092-ae38-6c1d99b736d7'	System	17 Oct 2020 07:45:22
User entered '17 Oct 2020 02:45:18'	System	17 Oct 2020 07:45:22

FDA-CBER-2022-1614-0005143

US3012098
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
Data entry locked.	System	11 Aug 2020 00:33:30
User entered '17 Oct 2020 00:01'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0005144

US3012098
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
Data entry locked.	System	11 Aug 2020 00:33:30
User entered '21 Oct 2020 23:59'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0005145

US3012098
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
Data entry locked.	System	11 Aug 2020 00:33:30
User entered 'Day 78'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0005146

US3012098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:12

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) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-10-28T19:49:32', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '0606bb89-6142-4807-9171-db2c61880860'	System	29 Oct 2020 00:49:47
User entered 'No (N)'	System	29 Oct 2020 00:49:47

US3012098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:12

Have you been exposed to someone with 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) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-10-28T19:49:35', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '0606bb89-6142-4807-9171-db2c61880860'	System	29 Oct 2020 00:49:47
User entered 'No (N)'	System	29 Oct 2020 00:49:47

US3012098
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-10-28T19:49:41', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: '0606bb89-6142-4807-9171-db2c61880860'	System	29 Oct 2020 00:49:47
User entered '28 Oct 2020 19:49:41'	System	29 Oct 2020 00:49:47

FDA-CBER-2022-1614-0005149

US3012098
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
Data entry locked.	System	11 Aug 2020 00:33:30
User entered '24 Oct 2020 00:01'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0005150

US3012098
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
Data entry locked.	System	11 Aug 2020 00:33:30
User entered '28 Oct 2020 23:59'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0005151

US3012098
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
Data entry locked.	System	11 Aug 2020 00:33:30
User entered 'Day 92'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0005152

US3012098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:12

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) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-11-10T18:00:44', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'dcf06b24-32dc-42a3-b30c-ef83706a00b0'	System	11 Nov 2020 00:01:03
User entered 'No (N)'	System	11 Nov 2020 00:01:03

US3012098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:12

Have you been exposed to someone with 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) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-11-10T18:00:48', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'dcf06b24-32dc-42a3-b30c-ef83706a00b0'	System	11 Nov 2020 00:01:03
User entered 'No (N)'	System	11 Nov 2020 00:01:03

US3012098
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f6748508af78273b)', Time: '2020-11-10T18:00:56', User OID: 'PatientReportedOutcome (US3012098)', ODM File OID: 'dcf06b24-32dc-42a3-b30c-ef83706a00b0'	System	11 Nov 2020 00:01:03
User entered '10 Nov 2020 18:00:56'	System	11 Nov 2020 00:01:03

FDA-CBER-2022-1614-0005155

US3012098
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
Data entry locked.	System	11 Aug 2020 00:33:30
User entered '07 Nov 2020 00:01'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0005156

US3012098
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 20:40:13
Data entry locked.	System	11 Aug 2020 00:33:30
User entered '11 Nov 2020 23:59'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0005157

US3012098
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:22:57
Data entry locked.	System	11 Aug 2020 00:33:30
User entered 'Day 99'	System	11 Aug 2020 00:33:30

FDA-CBER-2022-1614-0005158

US3012098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:12

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) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:22:57

US3012098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:12

Have you been exposed to someone with 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) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:22:57

US3012098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:12

Please 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) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:22:57

US3012098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:12

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) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:22:57

US3012098
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:22:57

US3012098
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:22:57

US3012098
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:22:57

FDA-CBER-2022-1614-0005165

US3012098
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:22:57

US3012098
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:22:57

FDA-CBER-2022-1614-0005167

US3012098
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:22:57

FDA-CBER-2022-1614-0005168

US3012098
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:22:57

US3012098
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:22:57

US3012098
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:22:57

US3012098
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:22:57

US3012098
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:22:57

US3012098
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:22:57

US3012098
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:22:57

FDA-CBER-2022-1614-0005175

US3012098
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:22:57

US3012098
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:22:57

US3012098
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:22:57

US3012098
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:22:57

FDA-CBER-2022-1614-0005179

US3012098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:12

Please 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) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:22:57

US3012098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:12

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) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:22:57

US3012098

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:12

Please 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) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:22:57

US3012098
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:22:57

US3012098
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:22:57
Data entry locked.	System	11 Aug 2020 00:33:30
User entered '14 Nov 2020 00:01'	System	11 Aug 2020 00:33:30

US3012098
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:22:57
Data entry locked.	System	11 Aug 2020 00:33:30
User entered '18 Nov 2020 23:59'	System	11 Aug 2020 00:33:30

US3012098
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 03:22:57

FDA-CBER-2022-1614-0005186

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:12

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) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:12

Have you been exposed to someone with 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) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:12

Please 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) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:12

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) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09

US3012098
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09

FDA-CBER-2022-1614-0005191

US3012098
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09

FDA-CBER-2022-1614-0005192

US3012098
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09

FDA-CBER-2022-1614-0005193

US3012098
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09

FDA-CBER-2022-1614-0005194

US3012098
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09

FDA-CBER-2022-1614-0005195

US3012098
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09

FDA-CBER-2022-1614-0005196

US3012098
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09

US3012098
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09

FDA-CBER-2022-1614-0005198

US3012098
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09

FDA-CBER-2022-1614-0005199

US3012098
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09

FDA-CBER-2022-1614-0005200

US3012098
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09

FDA-CBER-2022-1614-0005201

US3012098
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09

FDA-CBER-2022-1614-0005202

US3012098
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09

FDA-CBER-2022-1614-0005203

US3012098
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09

FDA-CBER-2022-1614-0005204

US3012098
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09

FDA-CBER-2022-1614-0005205

US3012098
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09

FDA-CBER-2022-1614-0005206

US3012098
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09

FDA-CBER-2022-1614-0005207

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:12

Please 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) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:12

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) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:12

Please 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) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09

US3012098
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09

FDA-CBER-2022-1614-0005211

US3012098
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 03:22:57

US3012098
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 03:22:57

US3012098
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 03:22:57

FDA-CBER-2022-1614-0005214

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:12

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) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:12

Have you been exposed to someone with 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) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:12

Please 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) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:12

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) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09

US3012098
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09

FDA-CBER-2022-1614-0005219

US3012098
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09

FDA-CBER-2022-1614-0005220

US3012098
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09

FDA-CBER-2022-1614-0005221

US3012098
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09

FDA-CBER-2022-1614-0005222

US3012098
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09

FDA-CBER-2022-1614-0005223

US3012098
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09

FDA-CBER-2022-1614-0005224

US3012098
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09

FDA-CBER-2022-1614-0005225

US3012098
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09

FDA-CBER-2022-1614-0005226

US3012098
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09

FDA-CBER-2022-1614-0005227

US3012098
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09

FDA-CBER-2022-1614-0005228

US3012098
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09

FDA-CBER-2022-1614-0005229

US3012098
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09

FDA-CBER-2022-1614-0005230

US3012098
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09

FDA-CBER-2022-1614-0005231

US3012098
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09

FDA-CBER-2022-1614-0005232

US3012098
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09

FDA-CBER-2022-1614-0005233

US3012098
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09

FDA-CBER-2022-1614-0005234

US3012098
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09

FDA-CBER-2022-1614-0005235

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:12

Please 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) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:12

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) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09

US3012098

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:54:12

Please 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) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09

US3012098
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09

FDA-CBER-2022-1614-0005239

US3012098
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 03:22:57

US3012098
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 09 Jun 2021 14:54:12
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:22:57
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 03:22:57

US3012098
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:54:12
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:50:16

FDA-CBER-2022-1614-0005242

US3012098
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:54:12
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '03 Nov 2020'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:50:16

FDA-CBER-2022-1614-0005243

US3012098
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:54:12
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Contact Made (CONTACT MADE)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:50:16

FDA-CBER-2022-1614-0005244

US3012098
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 09 Jun 2021 14:54:12
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:50:16

FDA-CBER-2022-1614-0005245

US3012098
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:54:12
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'No (N)' reason for change: New Information	Jennifer Leyva (b) (4) (b) (4)	02 Dec 2020 16:35:36
User entered 'Yes (Y)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:50:34

US3012098
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 09 Jun 2021 14:54:12
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	02 Dec 2020 16:35:36
User entered '1'	System	03 Nov 2020 20:50:34

US3012098
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 09 Jun 2021 14:54:12
Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:43:56
User entered 'Yes (Y)' reason for change: New Information	Jennifer Leyva (b) (4) (b) (4)	01 Oct 2020 21:57:02
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	08 Sep 2020 13:17:34

US3012098
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:54:12
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:32:15
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:28
User entered 'USA-US006-2020-mRNA-1273-P301000002'	System	02 Oct 2020 12:35:23
User entered 'New'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0005249

US3012098
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:54:12
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:32:20
User closed query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	21 Oct 2020 16:46:43
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal inflammatory conditions, HLT: Colitis (excl infective), PT: Colitis, LLT: Colitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 14:29:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 14:29:44
Data point term sent to Coder	System	20 Oct 2020 14:28:21
Query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.' answered with 'Updated' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	20 Oct 2020 14:28:07
Coding entries removed.	Jennifer Leyva (b) (4) (b) (4)	20 Oct 2020 14:28:01
User entered 'Colitis' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	20 Oct 2020 14:28:01
User opened query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 15:20:24
User closed query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	12 Oct 2020 15:57:25
Query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.' answered with 'Unknown. Subject is currently in ICU and unable to speak or provide further information.' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	09 Oct 2020 14:44:08
User opened query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 14:07:41
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Gastrointestinal and abdominal pains (excl oral and throat), PT: Abdominal pain, LLT: Abdominal pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 21:59:57

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US3012098
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:54:12
Adverse event

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)	01 Oct 2020 21:59:57
Data point term sent to Coder	System	01 Oct 2020 21:59:31
User entered 'Abdominal pain'	Jennifer Leyva (b) (4) (b) (4)	01 Oct 2020 21:58:38

US3012098
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:54:12
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:32:28
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	01 Oct 2020 21:58:38

FDA-CBER-2022-1614-0005252

US3012098
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:54:12
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:32:30
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	01 Oct 2020 21:58:38

FDA-CBER-2022-1614-0005253

US3012098
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:54:12
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:32:32
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	01 Oct 2020 21:58:38

US3012098
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:54:12
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User closed query 'PV Query: The onset date for the event of colitis was updated from 26 Sep 2020 to 24 Sep 2020 (2 days prior to hospital admission). Please provide any signs, symptoms or details that led to the updated onset date for this event.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	06 Nov 2020 18:24:25
Query 'PV Query: The onset date for the event of colitis was updated from 26 Sep 2020 to 24 Sep 2020 (2 days prior to hospital admission). Please provide any signs, symptoms or details that led to the updated onset date for this event.' answered with 'Abdominal pain which was later diagnosed as Colitis began 24-Sep-2020' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	05 Nov 2020 17:51:43
User opened query 'PV Query: The onset date for the event of colitis was updated from 26 Sep 2020 to 24 Sep 2020 (2 days prior to hospital admission). Please provide any signs, symptoms or details that led to the updated onset date for this event.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 17:18:01
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	30 Oct 2020 16:00:12
User closed query 'Source states 24Sept20. Please review and clarify. ' (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	30 Oct 2020 16:00:10
Query 'Source states 24Sept20. Please review and clarify. ' answered with 'updated' (Site from CRA).	Jennifer Leyva (b) (4) (b) (4)	29 Oct 2020 20:22:37
User entered '24 Sep 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	29 Oct 2020 20:22:01
User opened query 'Source states 24Sept20. Please review and clarify. ' (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:32:57
User entered '26 Sep 2020'	Jennifer Leyva (b) (4) (b) (4)	01 Oct 2020 21:58:38

FDA-CBER-2022-1614-0005255

US3012098
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:54:12
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:33:00
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	01 Oct 2020 21:58:38

FDA-CBER-2022-1614-0005256

US3012098
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:54:12
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	01 Oct 2020 21:58:38

FDA-CBER-2022-1614-0005257

US3012098
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:54:12
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	30 Oct 2020 16:00:39
User closed query 'Source does not have an end date. Please review and clarify. ' (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	30 Oct 2020 16:00:37
Query 'Source does not have an end date. Please review and clarify. ' answered with 'source updated' (Site from CRA).	Jennifer Leyva (b) (4) (b) (4)	29 Oct 2020 20:22:55
User opened query 'Source does not have an end date. Please review and clarify. ' (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:33:17
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	20 Oct 2020 14:28:23
User entered 'No (N)' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	20 Oct 2020 14:28:23
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	20 Oct 2020 14:28:01
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	01 Oct 2020 21:58:38

US3012098
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:54:12
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	30 Oct 2020 16:00:40
DataPoint Un-verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:33:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:33:35
User closed query 'PV Query: Please provide the event end date of abdominal pain (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	21 Oct 2020 16:47:05
Query 'PV Query: Please provide the event end date of abdominal pain (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'updated' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	20 Oct 2020 14:28:41
User entered '30 Sep 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	20 Oct 2020 14:28:01
User opened query 'PV Query: Please provide the event end date of abdominal pain (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 15:19:31
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	01 Oct 2020 21:58:38

US3012098
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:54:12
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:33:39
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	12 Oct 2020 15:57:30
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Unknown' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	09 Oct 2020 14:44:17
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 13:46:00
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	01 Oct 2020 21:58:38

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US3012098
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:54:12
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	01 Oct 2020 21:58:38

FDA-CBER-2022-1614-0005261

US3012098
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:54:12
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:33:41
User entered 'Grade 3/Severe (Grade 3/Severe)'	Jennifer Leyva (b) (4) (b) (4)	01 Oct 2020 21:58:38

US3012098
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:54:12
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:33:42
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	01 Oct 2020 22:01:28
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	01 Oct 2020 21:58:38
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	01 Oct 2020 21:58:38

FDA-CBER-2022-1614-0005263

US3012098
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:54:12
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:33:43
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	01 Oct 2020 21:58:38

US3012098
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:54:12
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:33:45
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	01 Oct 2020 21:58:38

US3012098
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:54:12
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4), (b) (6)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:33:50
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	05 Oct 2020 12:26:17
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Not yet discharged. Currently hospitalized.' (Site from System).	Jennifer Leyva (b) (4) (b) (4)	01 Oct 2020 22:02:31
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	01 Oct 2020 22:01:28
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	01 Oct 2020 22:01:28
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	01 Oct 2020 22:01:28
User entered '1' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	01 Oct 2020 22:01:28
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	01 Oct 2020 21:58:38
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	01 Oct 2020 21:58:38

US3012098
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:54:12
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:33:52
User entered '26 Sep 2020'	Jennifer Leyva (b) (4) (b) (4)	01 Oct 2020 21:58:38

US3012098
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:54:12
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 15:18:18
DataPoint Un-verified.	Jennifer Leyva (b) (4) (b) (4)	10 Nov 2020 15:16:36
User entered '12 Oct 2020' reason for change: New Information	Jennifer Leyva (b) (4) (b) (4)	10 Nov 2020 15:16:36
User closed query 'PV Query: The hospital discharge date is reported as 13 Oct 2020 for event Colitis; however, the discharge date is reported as 12 Oct 2020 for the event c-diff. Please update as applicable.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Nov 2020 15:21:27
Query 'PV Query: The hospital discharge date is reported as 13 Oct 2020 for event Colitis; however, the discharge date is reported as 12 Oct 2020 for the event c-diff. Please update as applicable.' answered with 'Corrected on C-Diff CRF' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	30 Oct 2020 19:12:00
User opened query 'PV Query: The hospital discharge date is reported as 13 Oct 2020 for event Colitis; however, the discharge date is reported as 12 Oct 2020 for the event c-diff. Please update as applicable.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 13:45:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:33:54
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	21 Oct 2020 16:47:13
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'updated' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	20 Oct 2020 14:28:44
User entered '13 Oct 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	20 Oct 2020 14:28:01
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 15:20:40
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	12 Oct 2020 15:57:35

US3012098
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:54:12
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'Will provide when available. Subject is currently hospitalized.' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	09 Oct 2020 14:44:35
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 14:08:04
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	01 Oct 2020 21:58:38

US3012098
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:54:12
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:34:17
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	01 Oct 2020 21:58:38

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US3012098
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:54:12
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:34:18
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	01 Oct 2020 21:58:38

US3012098
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:54:12
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:34:20
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	01 Oct 2020 21:58:38

US3012098
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:54:12
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:34:21
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	01 Oct 2020 21:58:38

US3012098
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:54:12
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:34:23
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	01 Oct 2020 21:58:38

FDA-CBER-2022-1614-0005274

US3012098
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:54:12
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:34:24
User entered 'Not Related (NOT RELATED)'	Jennifer Leyva (b) (4) (b) (4)	01 Oct 2020 21:58:38

US3012098
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:54:12
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:34:25
User entered 'Not Related (NOT RELATED)'	Jennifer Leyva (b) (4) (b) (4)	01 Oct 2020 21:58:38

FDA-CBER-2022-1614-0005276

US3012098
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:54:12
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:34:27
User entered 'Not Applicable (NOT APPLICABLE)'	Jennifer Leyva (b) (4) (b) (4)	01 Oct 2020 21:58:38

US3012098
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:54:12
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	30 Oct 2020 16:00:52
User closed query 'Source does not have a check box in section for Other Action Taken. Please review and clarify. ' (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	30 Oct 2020 16:00:51
Query 'Source does not have a check box in section for Other Action Taken. Please review and clarify. ' answered with 'updated' (Site from CRA).	Jennifer Leyva (b) (4) (b) (4)	29 Oct 2020 20:23:02
User entered '0' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	29 Oct 2020 20:22:01
User opened query 'Source does not have a check box in section for Other Action Taken. Please review and clarify. ' (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:35:23
DataPoint Un-verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:34:30
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:34:29
User entered '1'	Jennifer Leyva (b) (4) (b) (4)	01 Oct 2020 21:58:38

US3012098
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:54:12
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	30 Oct 2020 16:00:56
User closed query ' SAE narrative indicates ConMed taken for this event but not indicated on CRF or on AE source page. Please clarify. ' (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	30 Oct 2020 16:00:54
Query ' SAE narrative indicates ConMed taken for this event but not indicated on CRF or on AE source page. Please clarify. ' answered with 'updated' (Site from CRA).	Jennifer Leyva (b) (4) (b) (4)	29 Oct 2020 20:23:12
User entered '1' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	29 Oct 2020 20:22:01
User opened query ' SAE narrative indicates ConMed taken for this event but not indicated on CRF or on AE source page. Please clarify. ' (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:37:09
Query 'SAE narrative indicates ConMed taken for this event but not indicated on CRF. Please clarify. ' canceled (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:36:56
User opened query 'SAE narrative indicates ConMed taken for this event but not indicated on CRF. Please clarify. ' (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:36:43
DataPoint Un-verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:36:13
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:35:25
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	01 Oct 2020 21:58:38

FDA-CBER-2022-1614-0005279

US3012098
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:54:12
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:15:45
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:26
User closed query 'Per DM CLR: Other action taken = Concomitant Procedure. Please disregard query in Con procedure, please note that Diagnostic procedures are not considered treatment. Please review and add therapeutic procedure as appropriate or update Treatment Required field.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 17:48:23
Query 'Per DM CLR: Other action taken = Concomitant Procedure. Please disregard query in Con procedure, please note that Diagnostic procedures are not considered treatment. Please review and add therapeutic procedure as appropriate or update Treatment Required field.' answered with 'updated' (Site from DM).	Pamela Fidler (b) (4) (b) (4) (b) (4)	08 Mar 2021 17:04:09
Signature has been broken.	Pamela Fidler (b) (4) (b) (4) (b) (4)	08 Mar 2021 17:04:01
User entered '0' reason for change: Data Entry Error	Pamela Fidler (b) (4) (b) (4) (b) (4)	08 Mar 2021 17:04:01
User opened query 'Per DM CLR: Other action taken = Concomitant Procedure. Please disregard query in Con procedure, please note that Diagnostic procedures are not considered treatment. Please review and add therapeutic procedure as appropriate or update Treatment Required field.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 02:43:42
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Un-verified.	Jennifer Leyva (b) (4) (b) (4)	03 Mar 2021 18:14:40
User entered '1' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	03 Mar 2021 18:14:40
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:35:27
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	01 Oct 2020 21:58:38

FDA-CBER-2022-1614-0005280

US3012098
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:54:12
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:35:35
User closed query 'PV Query: Please provide the final event outcome of abdominal pain, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	21 Oct 2020 16:47:48
Query 'PV Query: Please provide the final event outcome of abdominal pain, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	20 Oct 2020 14:28:48
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	20 Oct 2020 14:28:01
User opened query 'PV Query: Please provide the final event outcome of abdominal pain, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 15:19:51
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	12 Oct 2020 15:57:40
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'To be updated when applicable.' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	09 Oct 2020 14:44:54
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 13:48:48
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jennifer Leyva (b) (4) (b) (4)	01 Oct 2020 21:58:38

US3012098
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:54:12
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:35:36
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	01 Oct 2020 21:58:38

US3012098
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:54:12
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:15:48
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Un-verified.	Jennifer Leyva (b) (4) (b) (4)	13 Jan 2021 18:16:28
User entered 'PATIENT REPORTED TO ER ON 26-SEP-2020 WITH SEVERE ABDOMINAL PAIN, GENERAL/ENTIRE AREA. WAS ADMITTED AND GIVEN UNKNOWN MEDICATIONS FOR PAIN and subsequently diagnosed with Colitis.' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	13 Jan 2021 18:16:28
User closed query 'PV Query: Does exacerbation of diastolic CHF meet criteria for separate AE/SAE reporting? If yes, please report accordingly. If no, please explain.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 16:31:01
User closed query 'PV Query: Subject had acute hypoxic respiratory failure secondary to COPD and exacerbation of diastolic congestive heart failure. Please add diastolic CHF to med history.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 16:30:59
User closed query 'PV Query: The patient was placed on bilevel positive airway pressure due to acute hypoxic respiratory failure. Please consider reporting additional SAE Acute hypoxic respiratory failure' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 16:30:57
User closed query 'PV Query: Please confirm if acute hypoxic respiratory failure met SAE criteria.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 16:30:48
Query 'PV Query: Does exacerbation of diastolic CHF meet criteria for separate AE/SAE reporting? If yes, please report accordingly. If no, please explain.' answered with 'Entered' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:22:47
Query 'PV Query: The patient was placed on bilevel positive airway pressure due to acute hypoxic respiratory failure. Please consider reporting additional SAE Acute hypoxic respiratory failure' answered with 'Added' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:21:09

US3012098
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:54:12
Narrative

Audit	User	Time (GMT)
Query 'PV Query: Please confirm if acute hypoxic respiratory failure met SAE criteria.' answered with 'Entered' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:21:00
Query 'PV Query: Subject had acute hypoxic respiratory failure secondary to COPD and exacerbation of diastolic congestive heart failure. Please add diastolic CHF to med history.' answered with 'Added' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:19:11
User closed query 'PV Query: Please consider merging SAE Colitis and SAE C. difficile and reporting as one event C. difficile colitis.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Nov 2020 13:27:03
Query 'PV Query: Please consider merging SAE Colitis and SAE C. difficile and reporting as one event C. difficile colitis.' answered with 'These are two separate events. Subject reported to hospital due to abdominal pain that was diagnosed as Colitis and while at the hospital, contracted C. Diff.' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	12 Nov 2020 17:46:27
User opened query 'PV Query: Does exacerbation of diastolic CHF meet criteria for separate AE/SAE reporting? If yes, please report accordingly. If no, please explain.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 15:55:38
User opened query 'PV Query: Subject had acute hypoxic respiratory failure secondary to COPD and exacerbation of diastolic congestive heart failure. Please add diastolic CHF to med history.' (Site from Safety).		11 Nov 2020 15:55:21
User opened query 'PV Query: Please consider merging SAE Colitis and SAE C. difficile and reporting as one event C. difficile colitis.' (Site from Safety).		11 Nov 2020 15:54:59
User opened query 'PV Query: The patient was placed on bilevel positive airway pressure due to acute hypoxic respiratory failure. Please consider reporting additional SAE Acute hypoxic respiratory failure' (Site from Safety).		11 Nov 2020 15:54:33
User opened query 'PV Query: Please confirm if acute hypoxic respiratory failure met SAE criteria.' (Site from Safety).		11 Nov 2020 15:54:00

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Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:54:12
Narrative

Audit	User	Time (GMT)
User closed query 'Per DM CLR: SAE Narrative indicates that an unknown medication was given for this AE. However, there is no corresponding ConMed record that match the information. Please reconcile and update applicable details accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 04:53:11
User closed query 'PV Query: It was reported in concomitant medication section that the subject was treated for a UTI while hospitalized. If UTI is a new finding, please assess whether it meets criteria for separate AE/SAE reporting.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	06 Nov 2020 18:25:22
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) (6) (b) (4), (b) (6)	06 Nov 2020 18:25:12
User closed query 'PV Query: Please provide results of lab (eg CBC, liver enzymes, pancreatic enzymes (amylase and lipase), and urinalysis), and diagnostic tests (i.e.abdominal CT, ultrasound) performed in evaluation of the event.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	06 Nov 2020 18:24:58
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	06 Nov 2020 18:24:49
Query 'PV Query: It was reported in concomitant medication section that the subject was treated for a UTI while hospitalized. If UTI is a new finding, please assess whether it meets criteria for separate AE/SAE reporting.' answered with 'Treatment was pre-emptive. Test results for UTI were negative.' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	05 Nov 2020 17:53:14

US3012098
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:54:12
Narrative

Audit	User	Time (GMT)
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 'Emailed to Safety_Moderna@iqvia on 04-NOV-2020' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	05 Nov 2020 17:52:51
Query 'PV Query: Please provide results of lab (eg CBC, liver enzymes, pancreatic enzymes (amylase and lipase), and urinalysis), and diagnostic tests (i.e.abdominal CT, ultrasound) performed in evaluation of the event.' answered with 'All diagnostic testing and con-meds have been entered.' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	05 Nov 2020 17:52:35
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'All Con-Meds and Diagnostic procedures have been entered' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	05 Nov 2020 17:52:06
User opened query 'PV Query: It was reported in concomitant medication section that the subject was treated for a UTI while hospitalized. If UTI is a new finding, please assess whether it meets criteria for separate AE/SAE reporting.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 17:18:10
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).		05 Nov 2020 17:16:47
User opened query 'PV Query: Please provide results of lab (eg CBC, liver enzymes, pancreatic enzymes (amylase and lipase), and urinalysis), and diagnostic tests (i.e.abdominal CT, ultrasound) performed in evaluation of the event.' (Site from Safety).		05 Nov 2020 17:16:37

US3012098
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:54:12
Narrative

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 17:16:27
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) (6) (b) (4), (b) (6) (b) (4), (b) (6)	05 Nov 2020 16:52:45
User closed query 'PV Query: Please provide results of lab (eg CBC, liver enzymes, pancreatic enzymes (amylase and lipase), and urinalysis), and diagnostic tests (i.e.abdominal CT, ultrasound) performed in evaluation of the event.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	05 Nov 2020 16:52:40
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so' answered with 'Hospital discharge summary sent to Moderna Safety team - 11/04/2020' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	04 Nov 2020 22:13:53
Query 'PV Query: Please provide results of lab (eg CBC, liver enzymes, pancreatic enzymes (amylase and lipase), and urinalysis), and diagnostic tests (i.e.abdominal CT, ultrasound) performed in evaluation of the event.' answered with 'Full lab panel run - normal results. Records sent to Moderna Safety Team - 11/04/20' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	04 Nov 2020 22:12:48
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	04 Nov 2020 14:11:03

US3012098
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:54:12
Narrative

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Entered' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	03 Nov 2020 22:14:52
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)	30 Oct 2020 13:44:06
User opened query 'PV Query: Please provide results of lab (eg CBC, liver enzymes, pancreatic enzymes (amylase and lipase), and urinalysis), and diagnostic tests (i.e.abdominal CT, ultrasound) performed in evaluation of the event.' (Site from Safety).		30 Oct 2020 13:43:28
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		30 Oct 2020 13:42:52
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:35:49
Query 'Per DM CLR: SAE Narrative indicates that an unknown medication was given for this AE. However, there is no corresponding ConMed record that match the information. Please reconcile and update applicable details accordingly. Otherwise, clarify.' answered with 'CM 21 updated' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	26 Oct 2020 12:31:15
User opened query 'Per DM CLR: SAE Narrative indicates that an unknown medication was given for this AE. However, there is no corresponding ConMed record that match the information. Please reconcile and update applicable details accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	24 Oct 2020 15:50:57

FDA-CBER-2022-1614-0005288

US3012098
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:54:12
Narrative

Audit	User	Time (GMT)
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) (6) (b) (4), (b) (6)	21 Oct 2020 16:49:20
User closed query 'PV Query: Please provide results of lab (eg CBC, liver enzymes, pancreatic enzymes (amylase and lipase), and urinalysis), and diagnostic tests (i.e.abdominal CT, ultrasound) performed in evaluation of the event.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	21 Oct 2020 16:49:05
User closed query 'PV Query: Did the subject have any additional symptoms besides abdominal pain (fever, vomiting, diarrhea/constipation, blood in the stool), fatigue, unusual amount of gas?' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	21 Oct 2020 16:48:46
User closed query 'PV Query: Please specify location of abdominal pain (paraumbilical, right upper/lower quadrant, etc)' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	21 Oct 2020 16:48:33
User closed query 'PV Query: Was the subject tested for COVID-19 in the hospital? If yes, please provide results.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	21 Oct 2020 16:48:21
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	21 Oct 2020 16:48:11
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 'Not received yet' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	20 Oct 2020 14:30:02
Query 'PV Query: Please provide results of lab (eg CBC, liver enzymes, pancreatic enzymes (amylase and lipase), and urinalysis), and diagnostic tests (i.e.abdominal CT, ultrasound) performed in evaluation of the event.' answered with 'Not received yet' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	20 Oct 2020 14:29:51

US3012098
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:54:12
Narrative

Audit	User	Time (GMT)
Query 'PV Query: Did the subject have any additional symptoms besides abdominal pain (fever, vomiting, diarrhea/constipation, blood in the stool), fatigue, unusual amount of gas?' answered with 'No' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	20 Oct 2020 14:29:41
Query 'PV Query: Please specify location of abdominal pain (paraumbilical, right upper/lower quadrant, etc)' answered with 'Entered. General/Entire Area.' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	20 Oct 2020 14:29:38
User entered 'PATIENT REPORTED TO ER ON 26-SEP-2020 WITH SEVERE ABDOMINAL PAIN, GENERAL/ENTIRE AREA. WAS ADMITTED AND GIVEN UNKNOWN MEDICATIONS FOR PAIN. NO DIAGNOSIS AS OF YET.' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	20 Oct 2020 14:29:27
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Records not received yet' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	20 Oct 2020 14:28:58
Query 'PV Query: Was the subject tested for COVID-19 in the hospital? If yes, please provide results.' answered with 'Yes. Negative.' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	20 Oct 2020 14:27:33
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)	19 Oct 2020 15:21:42
User opened query 'PV Query: Please provide results of lab (eg CBC, liver enzymes, pancreatic enzymes (amylase and lipase), and urinalysis), and diagnostic tests (i.e.abdominal CT, ultrasound) performed in evaluation of the event.' (Site from Safety).		19 Oct 2020 15:21:34

US3012098
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:54:12
Narrative

Audit	User	Time (GMT)
User opened query 'PV Query: Did the subject have any additional symptoms besides abdominal pain (fever, vomiting, diarrhea/constipation, blood in the stool), fatigue, unusual amount of gas?' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 15:21:17
User opened query 'PV Query: Please specify location of abdominal pain (paraumbilical, right upper/lower quadrant, etc)' (Site from Safety).		19 Oct 2020 15:21:07
User opened query 'PV Query: Was the subject tested for COVID-19 in the hospital? If yes, please provide results.' (Site from Safety).		19 Oct 2020 15:20:59
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		19 Oct 2020 15:20:07
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) (6) (b) (4), (b) (6) (b) (4), (b) (6)	12 Oct 2020 15:58:02
User closed query 'PV Query: Please provide results of lab (eg CBC, liver enzymes, pancreatic enzymes (amylase and lipase), and urinalysis), and diagnostic tests (i.e.abdominal CT, ultrasound) performed in evaluation of the event.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	12 Oct 2020 15:57:59
User closed query 'PV Query:Did the subject have any additional symptoms besides abdominal pain (fever, vomiting, diarrhea/constipation, blood in the stool), fatigue, unusual amount of gas?' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	12 Oct 2020 15:57:56
User closed query 'PV Query: Please specify location of abdominal pain (paraumbilical, right upper/lower quadrant, etc).' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	12 Oct 2020 15:57:53
User closed query 'PV Query: Was the subject tested for COVID-19 in the hospital? If yes, please provide results.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	12 Oct 2020 15:57:50

US3012098
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:54:12
Narrative

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	12 Oct 2020 15:57:47
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 'To be sent once collected' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	09 Oct 2020 14:45:47
Query 'PV Query: Please provide results of lab (eg CBC, liver enzymes, pancreatic enzymes (amylase and lipase), and urinalysis), and diagnostic tests (i.e.abdominal CT, ultrasound) performed in evaluation of the event.' answered with 'Unknown' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	09 Oct 2020 14:45:34
Query 'PV Query:Did the subject have any additional symptoms besides abdominal pain (fever, vomiting, diarrhea/constipation, blood in the stool), fatigue, unusual amount of gas?' answered with 'Unknown' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	09 Oct 2020 14:45:30
Query 'PV Query: Please specify location of abdominal pain (paraumbilical, right upper/lower quadrant, etc).' answered with 'Unknown' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	09 Oct 2020 14:45:24
Query 'PV Query: Was the subject tested for COVID-19 in the hospital? If yes, please provide results.' answered with 'Unknown' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	09 Oct 2020 14:45:17
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'No other information is known at this time as subject is in ICU and cannot speak.' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	09 Oct 2020 14:45:13

US3012098
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:54:12
Narrative

Audit	User	Time (GMT)
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)	09 Oct 2020 14:21:12
User opened query 'PV Query: Please provide results of lab (eg CBC, liver enzymes, pancreatic enzymes (amylase and lipase), and urinalysis), and diagnostic tests (i.e.abdominal CT, ultrasound) performed in evaluation of the event.' (Site from Safety).		09 Oct 2020 14:20:54
User opened query 'PV Query:Did the subject have any additional symptoms besides abdominal pain (fever, vomiting, diarrhea/constipation, blood in the stool), fatigue, unusual amount of gas?' (Site from Safety).		09 Oct 2020 14:09:42
User opened query 'PV Query: Please specify location of abdominal pain (paraumbilical, right upper/lower quadrant, etc).' (Site from Safety).		09 Oct 2020 14:09:00
User opened query 'PV Query: Was the subject tested for COVID-19 in the hospital? If yes, please provide results.' (Site from Safety).		09 Oct 2020 14:08:30
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		09 Oct 2020 14:07:20
User entered 'Patient reported to ER on 26-SEP-2020 with severe abdominal pain. Was admitted and given unknown medications for pain. No diagnosis as of yet.'	Jennifer Leyva (b) (4) (b) (4)	01 Oct 2020 21:58:38

US3012098
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:54:12
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '1'	System	01 Oct 2020 21:58:38

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US3012098
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:54:12
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '1'	System	01 Oct 2020 21:58:38

FDA-CBER-2022-1614-0005295

US3012098
Folder: Adverse Events
Form: Adverse Events (1)
Generated On: 09 Jun 2021 14:54:12
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '0'	System	01 Oct 2020 21:58:38

FDA-CBER-2022-1614-0005296

US3012098
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 14:54:12
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:40:06
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	14 Oct 2020 13:50:11
User entered 'USA-US006-2020-mRNA-1273-P301000002'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	14 Oct 2020 13:50:06

FDA-CBER-2022-1614-0005297

US3012098
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 14:54:12
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	09 Dec 2020 15:43:01
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Clostridia infections, PT: Clostridium difficile infection, LLT: Clostridium difficile infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Dec 2020 19:35:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Dec 2020 19:35:15
Data point term sent to Coder	System	04 Dec 2020 19:34:28
DataPoint Un-verified.	Jennifer Leyva (b) (4) (b) (4)	04 Dec 2020 19:33:58
Coding entries removed.	Jennifer Leyva (b) (4) (b) (4)	04 Dec 2020 19:33:58
User entered 'CLOSTRIDIUM DIFFICILE' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	04 Dec 2020 19:33:58
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:40:07
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Clostridia infections, PT: Clostridium difficile infection, LLT: Clostridium difficile infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 23:36:21
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 23:36:21
Data point term sent to Coder	System	13 Oct 2020 22:06:26
User entered 'clostricfium difficile'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 22:05:41

US3012098
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 14:54:12
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:40:09
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 22:05:41

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US3012098
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 14:54:12
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:40:11
User entered 'No (N)'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 22:05:41

US3012098
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 14:54:12
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:40:13
User entered 'No (N)'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 22:05:41

US3012098
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 14:54:12
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:40:19
User entered '29 Sep 2020'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 22:05:41

US3012098
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 14:54:12
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:40:21
User entered empty.	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 22:05:41

US3012098
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 14:54:12
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	13 Oct 2020 22:05:41

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US3012098
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 14:54:12
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:54:08
DataPoint Un-verified.	Jennifer Leyva (b) (4) (b) (4)	05 Nov 2020 17:54:54
User entered 'No (N)' reason for change: New Information	Jennifer Leyva (b) (4) (b) (4)	05 Nov 2020 17:54:54
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:40:23
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 22:05:41

US3012098
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 14:54:12
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:54:10
User closed query 'PV Query: Please provide the event end date of clostridium difficile (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	06 Nov 2020 18:27:01
Query 'PV Query: Please provide the event end date of clostridium difficile (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'updated' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	05 Nov 2020 17:55:20
DataPoint Un-verified.	Jennifer Leyva (b) (4) (b) (4)	05 Nov 2020 17:54:54
User entered '25 Oct 2020' reason for change: New Information	Jennifer Leyva (b) (4) (b) (4)	05 Nov 2020 17:54:54
User opened query 'PV Query: Please provide the event end date of clostridium difficile (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 17:17:21
User closed query 'PV Query: Please provide the event end date of clostridium difficile (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Nov 2020 15:42:21
Query 'PV Query: Please provide the event end date of clostridium difficile (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Per PI, will update if changes. Subject still recovering.' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	30 Oct 2020 19:11:23
User opened query 'PV Query: Please provide the event end date of clostridium difficile (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 13:47:31

US3012098
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 14:54:12
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:40:27
User closed query 'PV Query: Please provide the event end date of clostridium difficile (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	21 Oct 2020 16:45:17
Query 'PV Query: Please provide the event end date of clostridium difficile (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Ongoing' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	20 Oct 2020 14:30:15
User opened query 'PV Query: Please provide the event end date of clostridium difficile (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 15:24:21
User entered empty.	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 22:05:41

US3012098
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 14:54:12
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:40:28
User entered empty.	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 22:05:41

US3012098
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 14:54:12
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	13 Oct 2020 22:05:41

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US3012098
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 14:54:12
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:40:30
User entered 'Grade 3/Severe (Grade 3/Severe)'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 22:05:41

US3012098
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 14:54:12
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:40:32
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	13 Oct 2020 22:37:12
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	13 Oct 2020 22:05:41
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 22:05:41

US3012098
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 14:54:12
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:40:34
User entered '0'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 22:05:41

US3012098
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 14:54:12
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:40:36
User entered '0'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 22:05:41

US3012098
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 14:54:12
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:43:00
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	13 Oct 2020 22:38:02
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).	System	13 Oct 2020 22:38:02
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	13 Oct 2020 22:37:12
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	13 Oct 2020 22:37:12
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	13 Oct 2020 22:37:12
User entered '1' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	13 Oct 2020 22:37:12
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	13 Oct 2020 22:05:41
User entered '0'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 22:05:41

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US3012098
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 14:54:12
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:43:02
User closed query 'PV Query: The hospital admission date is reported as 26 Sep 2020 for event Abdominal Pain; however, the admission date is reported as 29 Sep 2020 for the event c-diff. Please confirm the admission date or update if applicable.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	21 Oct 2020 16:45:42
Query 'PV Query: The hospital admission date is reported as 26 Sep 2020 for event Abdominal Pain; however, the admission date is reported as 29 Sep 2020 for the event c-diff. Please confirm the admission date or update if applicable.' answered with 'updated' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	20 Oct 2020 14:30:39
User entered '26 Sep 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	20 Oct 2020 14:30:33
User opened query 'PV Query: The hospital admission date is reported as 26 Sep 2020 for event Abdominal Pain; however, the admission date is reported as 29 Sep 2020 for the event c-diff. Please confirm the admission date or update if applicable.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 15:25:00
User entered '29 Sep 2020'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 22:05:41

FDA-CBER-2022-1614-0005315

US3012098
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 14:54:12
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 15:18:30
User entered '12 Oct 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	10 Nov 2020 15:16:58
DataPoint Un-verified.	Jennifer Leyva (b) (4) (b) (4)	30 Oct 2020 19:09:54
User entered '13 Oct 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	30 Oct 2020 19:09:54
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:43:13
User entered '12 Oct 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	13 Oct 2020 22:38:02
User entered empty.	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 22:05:41

US3012098
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 14:54:12
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:43:15
User entered 'Yes (Y)' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	13 Oct 2020 22:38:02
User entered empty.	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 22:05:41

US3012098
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 14:54:12
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:43:17
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Oct 2020 22:38:16
User entered '5' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	13 Oct 2020 22:38:16
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Oct 2020 22:38:02
User entered 'UNK' (non-conformant).	Jennifer Leyva (b) (4) (b) (4)	13 Oct 2020 22:38:02
User entered empty.	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 22:05:41

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US3012098
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 14:54:12
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:43:19
User entered '0'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 22:05:41

FDA-CBER-2022-1614-0005319

US3012098
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 14:54:12
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:43:20
User entered '0'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 22:05:41

US3012098
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 14:54:12
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:43:22
User entered '0'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 22:05:41

US3012098
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 14:54:12
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:43:23
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 22:37:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 22:37:12
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	13 Oct 2020 22:37:12
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 22:05:41
User entered empty.	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 22:05:41

US3012098
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 14:54:12
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:43:27
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 22:37:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 22:37:12
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	13 Oct 2020 22:37:12
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 22:05:41
User entered empty.	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 22:05:41

US3012098
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 14:54:12
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:43:29
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 22:37:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 22:37:12
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	13 Oct 2020 22:37:12
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 22:05:41
User entered empty.	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 22:05:41

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US3012098
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 14:54:12
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:43:31
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	13 Oct 2020 22:37:12
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	13 Oct 2020 22:05:41
User entered '0'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 22:05:41

US3012098
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 14:54:12
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:43:33
User entered '1' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	13 Oct 2020 22:37:12
User entered '0'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 22:05:41

US3012098
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 14:54:12
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:43:35
User entered '0'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 22:05:41

US3012098
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 14:54:12
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:58:11
User closed query ' PV Query: Please provide the final event outcome of clostridium difficile (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	06 Nov 2020 18:27:19
Query ' PV Query: Please provide the final event outcome of clostridium difficile (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'updated' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	05 Nov 2020 17:55:24
DataPoint Un-verified.	Jennifer Leyva (b) (4) (b) (4)	05 Nov 2020 17:54:54
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Jennifer Leyva (b) (4) (b) (4)	05 Nov 2020 17:54:54
User opened query ' PV Query: Please provide the final event outcome of clostridium difficile (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 17:17:34
User closed query 'PV Query: Please provide the final event outcome of clostridium difficile (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Nov 2020 15:21:50
Query 'PV Query: Please provide the final event outcome of clostridium difficile (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Per PI, will update when applicable.' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	30 Oct 2020 19:11:38
User opened query 'PV Query: Please provide the final event outcome of clostridium difficile (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 13:48:02

US3012098
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 14:54:12
Outcome

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:43:37
User closed query 'PV Query: Please provide the final event outcome of clostridium difficile (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	21 Oct 2020 16:44:47
Query 'PV Query: Please provide the final event outcome of clostridium difficile (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available' answered with 'Correct as entered. Still ongoing' (Site from Safety).	Jennifer Leyva (b) (4) (b) (4)	20 Oct 2020 14:30:48
User opened query 'PV Query: Please provide the final event outcome of clostridium difficile (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 15:24:35
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 22:37:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 22:37:12
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	13 Oct 2020 22:37:12
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 22:05:41
User entered empty.	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 22:05:41

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US3012098
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 14:54:12
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:43:40
User entered empty.	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 22:05:41

US3012098
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 14:54:12
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:43:47
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	13 Oct 2020 22:41:15
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	13 Oct 2020 22:41:15
User entered 'Subject was admitted to hospital on 29-Sep-2020 due to abdominal pain, was diagnosed with C-Diff 5 days later, treated and released on 12-Oct-2020.' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	13 Oct 2020 22:41:15
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	13 Oct 2020 22:05:41
User entered empty.	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 22:05:41

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US3012098
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 14:54:12
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '1'	System	13 Oct 2020 22:05:41

FDA-CBER-2022-1614-0005332

US3012098
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 14:54:12
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '1'	System	13 Oct 2020 22:05:41

FDA-CBER-2022-1614-0005333

US3012098
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 09 Jun 2021 14:54:12
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '1'	System	13 Oct 2020 22:38:02

FDA-CBER-2022-1614-0005334

US3012098
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 14:54:12
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 16:02:49
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 16:29:40
User entered 'USA-US006-2020-mRNA-1273-P301000002'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 16:29:32

US3012098
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 14:54:12
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Respiratory failures (excl neonatal), PT: Acute respiratory failure, LLT: Acute respiratory failure - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Apr 2021 18:20:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Apr 2021 18:20:50
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Respiratory failures (excl neonatal), PT: Respiratory failure, LLT: Hypoxic respiratory failure - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Mar 2021 17:11:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Mar 2021 17:11:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Respiratory failures (excl neonatal), PT: Acute respiratory failure, LLT: Acute respiratory failure - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Dec 2020 13:03:02
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Dec 2020 13:03:02
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 16:02:51
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Respiratory failures (excl neonatal), PT: Respiratory failure, LLT: Hypoxic respiratory failure - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Nov 2020 22:18:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Nov 2020 22:18:49
Data point term sent to Coder	System	18 Nov 2020 21:21:43
User entered 'Acute Hypoxic Respiratory Failure'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:20:49

FDA-CBER-2022-1614-0005336

US3012098
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 14:54:12
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 16:02:53
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:20:49

US3012098
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 14:54:12
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 16:02:59
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:20:49

FDA-CBER-2022-1614-0005338

US3012098
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 14:54:12
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 16:03:01
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:20:49

US3012098
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 14:54:12
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:12:06
User entered '29 Sep 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 19:04:41
User entered '26 Sep 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 18:51:30
DataPoint Un-verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 16:03:18
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 16:03:15
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 06:30:46
Query 'Data is required. Please complete.' answered with 'UNK, start and end date not clear on discharge paperwork. Subject does not know dates either.' (Site from System).	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:21:40
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 21:20:49
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:20:49

FDA-CBER-2022-1614-0005340

US3012098
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 14:54:12
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:12:08
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:20:49

FDA-CBER-2022-1614-0005341

US3012098
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 14:54:12
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	18 Nov 2020 21:20:49

FDA-CBER-2022-1614-0005342

US3012098
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 14:54:12
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 16:07:51
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:20:49

FDA-CBER-2022-1614-0005343

US3012098
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 14:54:12
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:12:12
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	24 Nov 2020 18:51:30
User entered '12 Oct 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 18:51:30
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 06:34:12
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered with 'UNK, start and end date not clear on discharge paperwork. Subject does not know dates either.' (Site from System).	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:21:44
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	18 Nov 2020 21:20:49
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	18 Nov 2020 21:20:49
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:20:49

FDA-CBER-2022-1614-0005344

US3012098
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 14:54:12
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:12:15
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:20:49

US3012098
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 14:54:12
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	18 Nov 2020 21:20:49

FDA-CBER-2022-1614-0005346

US3012098
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 14:54:12
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:12:17
User entered 'Grade 4 (Grade 4)' reason for change: New Information	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 19:04:59
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:20:49

US3012098
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 14:54:12
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:12:18
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:20:49

FDA-CBER-2022-1614-0005348

US3012098
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 14:54:12
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:12:26
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:20:49

FDA-CBER-2022-1614-0005349

US3012098
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 14:54:12
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:12:28
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:20:49

US3012098
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 14:54:12
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:12:29
User entered '1'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:20:49

US3012098
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 14:54:12
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:29:00
User entered '29 Sep 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 20:25:48
User entered '26 Sep 2020'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:20:49

US3012098
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 14:54:12
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 16:11:17
User entered '12 Oct 2020'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:20:49

FDA-CBER-2022-1614-0005353

US3012098
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 14:54:12
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:12:36
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:20:49

FDA-CBER-2022-1614-0005354

US3012098
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 14:54:12
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:12:38
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:20:49

FDA-CBER-2022-1614-0005355

US3012098
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 14:54:12
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:12:40
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:20:49

US3012098
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 14:54:12
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:12:41
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:20:49

US3012098
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 14:54:12
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:12:43
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:20:49

US3012098
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 14:54:12
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 16:11:24
User entered 'Not Related (NOT RELATED)'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:20:49

FDA-CBER-2022-1614-0005359

US3012098
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 14:54:12
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 16:11:25
User entered 'Not Related (NOT RELATED)'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:20:49

FDA-CBER-2022-1614-0005360

US3012098
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 14:54:12
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 16:11:37
User entered 'Not Applicable (NOT APPLICABLE)'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:20:49

US3012098
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 14:54:12
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User closed query 'Per DM CLR: Response noted. Please review if CM#34 was given for this condition. If so, please reconcile event terms so there is an appropriate match and provide necessary update on 'other action take' field. Else, please provide explanation for no treatment for this serious AE.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Feb 2021 09:55:47
Query 'Per DM CLR: Response noted. Please review if CM#34 was given for this condition. If so, please reconcile event terms so there is an appropriate match and provide necessary update on 'other action take' field. Else, please provide explanation for no treatment for this serious AE.' answered with 'Patient withdrew consent for treatment and has declined requests for us to ask questions. This is unknown' (Site from DM).	Pamela Fidler (b) (4) (b) (4) (b) (4)	25 Jan 2021 17:18:23
User opened query 'Per DM CLR: Response noted. Please review if CM#34 was given for this condition. If so, please reconcile event terms so there is an appropriate match and provide necessary update on 'other action take' field. Else, please provide explanation for no treatment for this serious AE.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Jan 2021 06:47:34
User closed query 'Per DM CLR: Please note that there is no Con Med/Con Proc listed for treatment of this condition and treatment would be expected in a subject hospitalized. Diagnostic procedures are not considered treatment. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Jan 2021 06:47:34

US3012098
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 14:54:12
None

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note that there is no Con Med/Con Proc listed for treatment of this condition and treatment would be expected in a subject hospitalized. Diagnostic procedures are not considered treatment. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment. ' answered with 'No treatment was given. ' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	21 Jan 2021 20:01:55
User opened query 'Per DM CLR: Please note that there is no Con Med/Con Proc listed for treatment of this condition and treatment would be expected in a subject hospitalized. Diagnostic procedures are not considered treatment. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment. ' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 09:34:43
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	09 Dec 2020 17:07:25
DataPoint Un-verified.	Jennifer Leyva (b) (4) (b) (4)	09 Dec 2020 16:46:55
User entered '1' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	09 Dec 2020 16:46:55
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	09 Dec 2020 15:43:28
User closed query 'Per DM CLR: Other Action Taken = None, however there are Concomitant Medications recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	09 Dec 2020 11:48:46
Query 'Per DM CLR: Other Action Taken = None, however there are Concomitant Medications recorded that matches this AE during this timeframe. Please review and update this field. ' answered with 'Updated' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	07 Dec 2020 17:15:31
DataPoint Un-verified.	Jennifer Leyva (b) (4) (b) (4)	07 Dec 2020 17:15:27
User entered '0' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	07 Dec 2020 17:15:27
User opened query 'Per DM CLR: Other Action Taken = None, however there are Concomitant Medications recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4), (b) (6)	05 Dec 2020 11:01:33

US3012098
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 14:54:12
None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:29:04
User entered '1'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:20:49

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US3012098
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 14:54:12
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	09 Dec 2020 17:07:34
User entered '0' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	09 Dec 2020 16:46:55
DataPoint Un-verified.	Jennifer Leyva (b) (4) (b) (4)	07 Dec 2020 17:15:27
User entered '1' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	07 Dec 2020 17:15:27
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:29:05
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:20:49

FDA-CBER-2022-1614-0005365

US3012098
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 14:54:12
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:29:07
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:20:49

US3012098
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 14:54:12
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4), (b) (6) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:13:52
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jennifer Leyva (b) (4) (b) (4), (b) (6) (b) (4)	18 Nov 2020 21:20:49

US3012098
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 14:54:12
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:13:53
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:20:49

US3012098
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 14:54:12
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:13:55
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	18 Nov 2020 21:24:14
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	18 Nov 2020 21:24:14
User entered 'Subject reported to ER with abdominal pain. During course of hospitalization, subject experienced acute hypoxic respiratory failure. Unknown what date this occurred or how long it lasted.' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:24:14
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	18 Nov 2020 21:20:49
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:20:49

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US3012098
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 14:54:12
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '1'	System	18 Nov 2020 21:20:49

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US3012098
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 14:54:12
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '1'	System	18 Nov 2020 21:20:49

FDA-CBER-2022-1614-0005371

US3012098
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 09 Jun 2021 14:54:12
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '0'	System	18 Nov 2020 21:20:49

FDA-CBER-2022-1614-0005372

US3012098
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:54:12
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 16:12:23
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 16:30:19
User entered 'USA-US006-2020-mRNA-1273-P301000002'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 16:30:15

US3012098
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:54:12
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 16:12:25
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure congestive, LLT: Congestive cardiac failure aggravated - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Nov 2020 22:21:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Nov 2020 22:21:49
Data point term sent to Coder	System	18 Nov 2020 21:23:47
User entered 'Exacerbation of Diastolic CHF'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:22:46

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US3012098
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:54:12
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 16:12:28
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:22:46

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US3012098
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:54:12
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 16:12:30
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:22:46

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US3012098
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:54:12
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 16:12:33
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:22:46

US3012098
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:54:12
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:14:00
User entered '29 Sep 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 19:05:21
User entered '26 Sep 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 18:51:59
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 06:36:06
Query 'Data is required. Please complete.' answered with 'UNK, start and end date not clear on discharge paperwork. Subject does not know dates either.' (Site from System).	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:22:53
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 21:22:46
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:22:46

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US3012098
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:54:12
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:14:02
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:22:46

FDA-CBER-2022-1614-0005379

US3012098
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:54:12
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	18 Nov 2020 21:22:46

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US3012098
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:54:12
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 16:12:39
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:22:46

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US3012098
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:54:12
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:14:05
User entered '12 Oct 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 18:52:20
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	24 Nov 2020 18:51:59
User entered '13 Oct 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 18:51:59
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 06:37:16
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered with 'UNK, start and end date not clear on discharge paperwork. Subject does not know dates either.' (Site from System).	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:22:56
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	18 Nov 2020 21:22:46
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	18 Nov 2020 21:22:46
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:22:46

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US3012098
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:54:12
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:14:06
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:22:46

US3012098
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:54:12
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	18 Nov 2020 21:22:46

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US3012098
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:54:12
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:14:08
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 19:05:21
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:22:46

US3012098
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:54:12
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:14:10
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:22:46

FDA-CBER-2022-1614-0005386

US3012098
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:54:12
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:14:11
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:22:46

US3012098
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:54:12
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:14:13
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:22:46

FDA-CBER-2022-1614-0005388

US3012098
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:54:12
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:14:14
User entered '1'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:22:46

FDA-CBER-2022-1614-0005389

US3012098
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:54:12
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:29:14
User entered '29 Sep 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 20:26:13
User entered '26 Sep 2020'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:22:46

US3012098
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:54:12
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:14:26
User entered '12 Oct 2020'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:22:46

US3012098
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:54:12
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:14:29
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:22:46

US3012098
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:54:12
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:14:30
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:22:46

FDA-CBER-2022-1614-0005393

US3012098
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:54:12
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:14:32
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:22:46

FDA-CBER-2022-1614-0005394

US3012098
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:54:12
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:14:33
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:22:46

US3012098
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:54:12
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:14:34
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:22:46

US3012098
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:54:12
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 16:12:46
User entered 'Not Related (NOT RELATED)'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:22:46

US3012098
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:54:12
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 16:12:47
User entered 'Not Related (NOT RELATED)'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:22:46

FDA-CBER-2022-1614-0005398

US3012098
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:54:12
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 16:12:49
User entered 'Not Applicable (NOT APPLICABLE)'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:22:46

FDA-CBER-2022-1614-0005399

US3012098
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:54:12
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User closed query 'Per DM CLR-RQ: Response noted. Please review if there are medications given during this timeframe. If so, please reconcile event terms with CM indidcation so there is an appropriate match and provide necessary update on 'other action take' field. Else, please provide explanation for no treatment for this serious AE.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Feb 2021 09:57:15
Query 'Per DM CLR-RQ: Response noted. Please review if there are medications given during this timeframe. If so, please reconcile event terms with CM indidcation so there is an appropriate match and provide necessary update on 'other action take' field. Else, please provide explanation for no treatment for this serious AE.' answered with 'Patient withdrew consent for treatment and has declined requests for us to ask questions. This is unknown' (Site from DM).	Pamela Fidler (b) (4) (b) (4) (b) (4)	25 Jan 2021 17:18:32
User opened query 'Per DM CLR-RQ: Response noted. Please review if there are medications given during this timeframe. If so, please reconcile event terms with CM indidcation so there is an appropriate match and provide necessary update on 'other action take' field. Else, please provide explanation for no treatment for this serious AE.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Jan 2021 06:48:56
User closed query 'Per DM CLR: Please note that there is no Con Med/Con Proc listed for treatment of this condition and treatment would be expected in a subject hospitalized. Diagnostic procedures are not considered treatment. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Jan 2021 06:48:56

US3012098
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:54:12
None

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note that there is no Con Med/Con Proc listed for treatment of this condition and treatment would be expected in a subject hospitalized. Diagnostic procedures are not considered treatment. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment. ' answered with 'No treatment was given' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	21 Jan 2021 20:02:07
User opened query 'Per DM CLR: Please note that there is no Con Med/Con Proc listed for treatment of this condition and treatment would be expected in a subject hospitalized. Diagnostic procedures are not considered treatment. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment. ' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 09:34:54
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	09 Dec 2020 17:07:47
User entered '1' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	09 Dec 2020 16:47:16
User closed query 'Per DM CLR: Other Action Taken = None, however there are Concomitant Medications recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	09 Dec 2020 11:49:03
Query 'Per DM CLR: Other Action Taken = None, however there are Concomitant Medications recorded that matches this AE during this timeframe. Please review and update this field. ' answered with 'Updated' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	07 Dec 2020 17:16:43
DataPoint Un-verified.	Jennifer Leyva (b) (4) (b) (4)	07 Dec 2020 17:16:39
User entered '0' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	07 Dec 2020 17:16:39
User opened query 'Per DM CLR: Other Action Taken = None, however there are Concomitant Medications recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4), (b) (6)	05 Dec 2020 11:01:48
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:29:17
User entered '1'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:22:46

US3012098
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:54:12
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4), (b) (6) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	09 Dec 2020 17:07:49
User entered '0' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4), (b) (6) (b) (4)	09 Dec 2020 16:47:16
DataPoint Un-verified.	Jennifer Leyva (b) (4) (b) (4)	07 Dec 2020 17:16:39
User entered '1' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	07 Dec 2020 17:16:39
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:29:19
User entered '0'	Jennifer Leyva (b) (4) (b) (4), (b) (6) (b) (4)	18 Nov 2020 21:22:46

FDA-CBER-2022-1614-0005402

US3012098
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:54:12
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:29:22
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:22:46

FDA-CBER-2022-1614-0005403

US3012098
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:54:12
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:14:46
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:22:46

FDA-CBER-2022-1614-0005404

US3012098
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:54:12
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:14:48
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:22:46

US3012098
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:54:12
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:14:50
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	18 Nov 2020 21:24:56
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	18 Nov 2020 21:24:56
User entered 'SUBJECT REPORTED TO ER WITH ABDOMINAL PAIN. DURING COURSE OF HOSPITALIZATION, SUBJECT EXPERIENCED AN EXACERBATION OF CONGESTIVE HEART FAILURE. UNKNOWN WHAT DATE THIS OCCURRED OR HOW LONG IT LASTED.' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:24:56
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	18 Nov 2020 21:22:46
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	18 Nov 2020 21:22:46

FDA-CBER-2022-1614-0005406

US3012098
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:54:12
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '1'	System	18 Nov 2020 21:22:46

FDA-CBER-2022-1614-0005407

US3012098
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:54:12
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '1'	System	18 Nov 2020 21:22:46

FDA-CBER-2022-1614-0005408

US3012098
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 09 Jun 2021 14:54:12
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '0'	System	18 Nov 2020 21:22:46

FDA-CBER-2022-1614-0005409

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 14:54:12

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User closed query 'Medication of furosemide in source but not entered in EDC. Please consider adding to EDC. ' (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	30 Oct 2020 16:02:46
Query 'Medication of furosemide in source but not entered in EDC. Please consider adding to EDC. ' answered with 'Entered 28-Oct (CM #25)' (Site from CRA).	Jennifer Leyva (b) (4) (b) (4)	29 Oct 2020 20:15:44
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:53:08
User opened query 'Medication of furosemide in source but not entered in EDC. Please consider adding to EDC. ' (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:52:53
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:30:23

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:54:12

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:19:42
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:33:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:33:18
Data point term sent to Coder	System	11 Aug 2020 01:32:01
User entered 'albuterol'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:31:07

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:54:12
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:19:45
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:31:07

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:54:12
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:19:46
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'emphysema'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:31:07

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:54:12
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:19:48
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '90'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:31:07

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:54:12
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:19:49
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'ug (ug)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:31:07

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:54:12
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:23:24
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:31:07

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:54:12

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:23:28
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User closed query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	22 Sep 2020 10:33:39
Query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' answered with 'Correct as entered. Med can be used As Needed' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	21 Sep 2020 18:19:23
User opened query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	06 Sep 2020 12:43:58
User entered 'as needed (PRN)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:31:07

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:54:12
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:23:31
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:31:07

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:54:12
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:23:33
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:31:07

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:54:12
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:23:34
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:31:07

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:54:12
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:23:36
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Aug 2020 08:23:41
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'this is current medication.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:31:20
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 01:31:16
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Aug 2020 01:31:16
User entered 'Un UNK 2019' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:31:16
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Aug 2020 01:31:07
User entered 'uj UNK 2019' (non-conformant).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:31:07

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:54:12
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:23:37
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:31:07

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:54:12
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:23:39
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:31:07

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:54:12
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:23:40
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:31:07

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:54:12
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:23:41
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:31:07

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:54:12
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	11 Aug 2020 01:31:07

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US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	11 Aug 2020 01:31:07

FDA-CBER-2022-1614-0005427

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	11 Aug 2020 01:31:07

FDA-CBER-2022-1614-0005428

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:54:12

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:24:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User closed query 'Per DM CLR: Con Med ABILIFY was added on 10 AUG 2020. Please clarify if there was a WORSENING of the MH condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for additional regimen.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	22 Sep 2020 10:34:12
Query 'Per DM CLR: Con Med ABILIFY was added on 10 AUG 2020. Please clarify if there was a WORSENING of the MH condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for additional regimen.' answered with 'Updated. Date of Visit entered inadvertently.' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	21 Sep 2020 18:20:27
User opened query 'Per DM CLR: Con Med ABILIFY was added on 10 AUG 2020. Please clarify if there was a WORSENING of the MH condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for additional regimen.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	04 Sep 2020 11:14:19
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: OTHER ANTIPSYCHOTICS, PRODUCT: ARIPIPRAZOLE, PRODUCTSYNONYM: ABILIFY - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:33:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:33:18
Data point term sent to Coder	System	11 Aug 2020 01:33:01
User entered 'abilify'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:32:16

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:54:12
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:24:15
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:32:16

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:54:12
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:24:17
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'depression'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:32:16

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:54:12

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 16:35:02
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 22:22:05
User closed query 'Per source, dose per administration is recorded as, 15 mg. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 22:22:04
Query 'Per source, dose per administration is recorded as, 15 mg. Please verify and update EDC accordingly.' answered with 'Updated' (Site from CRA).	Jennifer Leyva (b) (4) (b) (4)	13 Apr 2021 20:44:04
Signature has been broken.	Jennifer Leyva (b) (4) (b) (4)	13 Apr 2021 20:43:41
User entered '15' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	13 Apr 2021 20:43:41
User opened query 'Per source, dose per administration is recorded as, 15 mg. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:25:01
DataPoint Un-verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:24:21
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:24:19
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '10'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:32:16

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:54:12
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:25:02
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'mg (mg)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:32:16

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:54:12
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:25:06
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:32:16

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:54:12
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:25:08
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'once daily (QD)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:32:16

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US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:54:12
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:25:10
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:32:16

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:54:12
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:25:12
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Oral (ORAL)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:32:16

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:54:12
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:25:13
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:32:16

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:54:12
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:25:17
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'UN UNK 2000' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	21 Sep 2020 18:20:13
User entered '10 Aug 2020'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:32:16

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:54:12
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:25:18
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:32:16

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:54:12
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:25:20
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:32:16

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:54:12
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:25:24
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:32:16

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:54:12
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:25:36
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:32:16

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:54:12
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '1'	System	11 Aug 2020 01:32:16

FDA-CBER-2022-1614-0005444

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '1'	System	11 Aug 2020 01:32:16

FDA-CBER-2022-1614-0005445

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '804 (804)'	System	11 Aug 2020 01:32:16

FDA-CBER-2022-1614-0005446

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:54:12

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:25:41
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
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)	11 Aug 2020 01:35:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:35:20
Data point term sent to Coder	System	11 Aug 2020 01:34:02
User entered 'atorvastatin'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:33:03

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 14:54:12
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:25:43
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:33:03

FDA-CBER-2022-1614-0005448

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 14:54:12
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:25:47
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'hypercholesterolemia'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:33:03

FDA-CBER-2022-1614-0005449

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 14:54:12
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:25:49
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '40'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:33:03

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 14:54:12
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:25:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'mg (mg)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:33:03

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 14:54:12
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:25:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:33:03

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 14:54:12
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:25:54
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'once daily (QD)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:33:03

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 14:54:12
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:25:56
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:33:03

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 14:54:12
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:25:57
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Oral (ORAL)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:33:03

FDA-CBER-2022-1614-0005455

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 14:54:12
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:25:58
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:33:03

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 14:54:12
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:26:00
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Aug 2020 08:28:13
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'this is current medication.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:33:07
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 01:33:03
User entered 'un UNK 2019'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:33:03

FDA-CBER-2022-1614-0005457

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 14:54:12
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:26:02
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:33:03

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 14:54:12
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:26:06
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:33:03

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 14:54:12
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:26:07
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:33:03

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 14:54:12
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:26:10
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:33:03

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 14:54:12
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '1'	System	11 Aug 2020 01:33:03

FDA-CBER-2022-1614-0005462

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '1'	System	11 Aug 2020 01:33:03

FDA-CBER-2022-1614-0005463

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '804 (804)'	System	11 Aug 2020 01:33:03

FDA-CBER-2022-1614-0005464

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:54:12

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:26:41
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ANTIADRENERGIC AGENTS, CENTRALLY ACTING, ATC: IMIDAZOLINE RECEPTOR AGONISTS, PRODUCT: CLONIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:17:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:17:10
Data point term sent to Coder	System	11 Aug 2020 01:34:02
User entered 'clonidine'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:33:54

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:54:12
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:26:59
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:33:54

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:54:12
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:27:02
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'anxiety, hypertension'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:33:54

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:54:12

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 16:35:02
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 22:22:19
User closed query 'Per source, dose per administration is recorded as 0.1 mg. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 22:22:17
Query 'Per source, dose per administration is recorded as 0.1 mg. Please verify and update EDC accordingly.' answered with 'Updated' (Site from CRA).	Jennifer Leyva (b) (4) (b) (4)	13 Apr 2021 21:04:49
Signature has been broken.	Jennifer Leyva (b) (4) (b) (4)	13 Apr 2021 21:04:18
User entered '0.1' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	13 Apr 2021 21:04:18
User opened query 'Per source, dose per administration is recorded as 0.1 mg. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:27:35
DataPoint Un-verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:27:06
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:27:04
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	01 Oct 2020 07:06:00
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'Updated' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	30 Sep 2020 22:56:54
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	06 Sep 2020 12:46:40
User entered '100'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:33:54

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:54:12
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 16:35:02
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 22:22:22
User closed query 'Per source, dose per administration is recorded as, mg. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 22:22:20
Query 'Per source, dose per administration is recorded as, mg. Please verify and update EDC accordingly.' answered with 'Updated' (Site from CRA).	Jennifer Leyva (b) (4) (b) (4)	13 Apr 2021 21:05:25
Signature has been broken.	Jennifer Leyva (b) (4) (b) (4)	13 Apr 2021 21:04:18
User entered 'mg (mg)' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	13 Apr 2021 21:04:18
User opened query 'Per source, dose per administration is recorded as, mg. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:27:50
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'ug (ug)' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	30 Sep 2020 22:56:37
User entered 'mg (mg)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:33:54

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:54:12
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:27:56
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:33:54

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US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:54:12
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:27:57
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'four times daily (QID)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:33:54

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:54:12
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:28:03
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:33:54

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:54:12
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:28:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Oral (ORAL)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:33:54

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:54:12
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:28:07
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:33:54

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:54:12
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:28:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Aug 2020 08:28:19
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'this is current medication.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:33:57
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 01:33:54
User entered 'un UNK 2000'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:33:54

FDA-CBER-2022-1614-0005475

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:54:12
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:28:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:33:54

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:54:12
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:28:12
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:33:54

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:54:12
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:28:14
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:33:54

FDA-CBER-2022-1614-0005478

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:54:12
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:28:16
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:33:54

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:54:12
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '4'	(b) (4), (b) (6) System	11 Aug 2020 01:33:54

FDA-CBER-2022-1614-0005480

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '1'	System	11 Aug 2020 01:33:54

FDA-CBER-2022-1614-0005481

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '804 (804)'	System	11 Aug 2020 01:33:54

FDA-CBER-2022-1614-0005482

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:54:12

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:28:19
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: DEXLANSOPRAZOLE, PRODUCTSYNONYM: DEXILANT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:35:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:35:20
Data point term sent to Coder	System	11 Aug 2020 01:35:02
User entered 'dexilant'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:34:45

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:54:12
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:28:21
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:34:45

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:54:12

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:28:23
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	22 Sep 2020 10:34:48
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'Reported as entered by subject.' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	21 Sep 2020 18:21:20
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	06 Sep 2020 12:47:36
User entered 'diverticulitis'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:34:45

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:54:12
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:28:25
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '60'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:34:45

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:54:12
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:28:27
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'mg (mg)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:34:45

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:54:12
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:28:29
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:34:45

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US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:54:12
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:28:31
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'once daily (QD)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:34:45

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:54:12
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:28:33
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:34:45

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:54:12
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:28:35
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Oral (ORAL)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:34:45

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:54:12
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:28:36
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:34:45

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:54:12
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:28:38
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Aug 2020 08:28:25
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'this is current medication.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:34:49
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 01:34:45
User entered 'un UNK 2017'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:34:45

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US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:54:12
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:28:39
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:34:45

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:54:12
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:28:41
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:34:45

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:54:12
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:28:43
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:34:45

FDA-CBER-2022-1614-0005496

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:54:12
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:28:45
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:34:45

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:54:12
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '1'	(b) (4), (b) (6) System	11 Aug 2020 01:34:45

FDA-CBER-2022-1614-0005498

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '1'	System	11 Aug 2020 01:34:45

FDA-CBER-2022-1614-0005499

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '804 (804)'	System	11 Aug 2020 01:34:45

FDA-CBER-2022-1614-0005500

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:54:12

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:28:48
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: OTHER HYPNOTICS AND SEDATIVES, PRODUCT: DOXEPIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 10:50:13
User coded data point as Term Coded data point by User (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 10:50:13
Data point term sent to Coder	System	11 Aug 2020 01:36:03
User entered 'doxepin'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:35:22

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:54:12
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:28:50
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:35:22

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:54:12
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:28:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'anxiety'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:35:22

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:54:12
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:28:53
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '300'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:35:22

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:54:12
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:28:55
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'mg (mg)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:35:22

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:54:12
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:28:57
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:35:22

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US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:54:12
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:28:59
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'once daily (QD)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:35:22

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:54:12
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:29:01
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:35:22

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:54:12
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:29:02
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Oral (ORAL)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:35:22

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:54:12
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:29:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:35:22

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:54:12

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:29:07
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Aug 2020 08:28:33
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'this is current medication.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:35:27
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 01:35:22
User entered 'un UNK 2015'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:35:22

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:54:12
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:29:08
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:35:22

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:54:12
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:29:10
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:35:22

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:54:12
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:29:12
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:35:22

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US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:54:12
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:29:13
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:35:22

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:54:12
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '1'	(b) (4), (b) (6) System	11 Aug 2020 01:35:22

FDA-CBER-2022-1614-0005516

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '1'	System	11 Aug 2020 01:35:22

FDA-CBER-2022-1614-0005517

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '804 (804)'	(b) (4), (b) (6) System	11 Aug 2020 01:35:22

FDA-CBER-2022-1614-0005518

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:54:12

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:29:18
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: OTHER COMBINATIONS OF NUTRIENTS, PRODUCT: FISH OIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:37:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:37:23
Data point term sent to Coder	System	11 Aug 2020 01:37:03
User entered 'fish oil'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:36:18

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 14:54:12
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:29:20
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:36:18

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 14:54:12
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:29:22
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'nutritional supplement'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:36:18

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 14:54:12
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:29:23
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '1000'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:36:18

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 14:54:12
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:29:25
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'mg (mg)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:36:18

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 14:54:12
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:29:26
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:36:18

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 14:54:12
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:29:27
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'once daily (QD)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:36:18

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 14:54:12
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:29:29
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:36:18

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 14:54:12
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:29:31
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Oral (ORAL)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:36:18

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 14:54:12
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:29:33
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:36:18

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 14:54:12
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:29:35
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Aug 2020 08:28:39
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'this is current medication.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:36:22
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 01:36:18
User entered 'un UNK 2015'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:36:18

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US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 14:54:12
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:29:38
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:36:18

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 14:54:12
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:29:40
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:36:18

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 14:54:12
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:29:42
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:36:18

FDA-CBER-2022-1614-0005532

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 14:54:12
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:29:45
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:36:18

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 14:54:12
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '1'	(b) (4), (b) (6) System	11 Aug 2020 01:36:18

FDA-CBER-2022-1614-0005534

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '1'	System	11 Aug 2020 01:36:18

FDA-CBER-2022-1614-0005535

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '804 (804)'	(b) (4), (b) (6) System	11 Aug 2020 01:36:18

FDA-CBER-2022-1614-0005536

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 14:54:12
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:29:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 18:22:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 18:22:49
Data point term sent to Coder	System	21 Sep 2020 18:22:18
Coding entries removed.	Jennifer Leyva (b) (4) (b) (4)	21 Sep 2020 18:21:46
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:39:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:39:16
Data point term sent to Coder	System	11 Aug 2020 01:38:04
User entered 'flonase'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:37:35

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 14:54:12
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:29:54
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User closed query 'Per DM CLR: Prophylaxis = Yes. However, please review if the response should be updated to 'No' instead as there is an MH recorded that matches this medication and used within the same timeframe. If yes, please update response as appropriate.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	22 Sep 2020 10:35:20
Query 'Per DM CLR: Prophylaxis = Yes. However, please review if the response should be updated to 'No' instead as there is an MH recorded that matches this medication and used within the same timeframe. If yes, please update response as appropriate.' answered with 'Updated' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	21 Sep 2020 18:21:50
User entered 'No (N)' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	21 Sep 2020 18:21:36
User opened query 'Per DM CLR: Prophylaxis = Yes. However, please review if the response should be updated to 'No' instead as there is an MH recorded that matches this medication and used within the same timeframe. If yes, please update response as appropriate.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	04 Sep 2020 13:30:38
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:37:35

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US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 14:54:12
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:29:58
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'seasonal allergies'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:37:35

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 14:54:12
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:30:00
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '50'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:37:35

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 14:54:12
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:30:03
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'ug (ug)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:37:35

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 14:54:12
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:30:06
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:37:35

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:54:12

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:30:08
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User closed query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	23 Sep 2020 13:43:30
Query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' answered with 'Correct as entered.' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	21 Sep 2020 18:22:00
User opened query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	04 Sep 2020 13:27:00
User entered 'as needed (PRN)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:37:35

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 14:54:12
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:30:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:37:35

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:54:12

Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:31:45
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate (i.e. Nasal).' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	23 Sep 2020 13:43:35
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate (i.e. Nasal).' answered with 'Updated' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	21 Sep 2020 18:21:53
User entered 'Nasal (NASAL)' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	21 Sep 2020 18:21:46
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate (i.e. Nasal).' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	04 Sep 2020 13:27:35
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:37:35

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 14:54:12
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:31:43
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:37:35

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 14:54:12
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:31:46
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Aug 2020 08:28:44
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'this is current medication.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:37:39
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 01:37:35
User entered 'un UNK 2015'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:37:35

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US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 14:54:12
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:31:48
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:37:35

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 14:54:12
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:31:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:37:35

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 14:54:12
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:31:53
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:37:35

FDA-CBER-2022-1614-0005550

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 14:54:12
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:31:55
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:37:35

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 14:54:12
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	11 Aug 2020 01:37:35

FDA-CBER-2022-1614-0005552

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	11 Aug 2020 01:37:35

FDA-CBER-2022-1614-0005553

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	11 Aug 2020 01:37:35

FDA-CBER-2022-1614-0005554

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:54:12

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:32:07
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STEROIDS, PRODUCT: CHONDROITIN;GLUCOSAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:40:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:40:17
Data point term sent to Coder	System	11 Aug 2020 01:39:04
User entered 'glucosamine chondroitin'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:38:27

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:54:12

Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	16 Apr 2021 16:20:31
User closed query 'Per source, this ConMed is not recorded as used for Prophylaxis. Please verify and update EDC/source accordingly.' (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	16 Apr 2021 16:20:29
Query 'Per source, this ConMed is not recorded as used for Prophylaxis. Please verify and update EDC/source accordingly.' answered with 'source updated' (Site from CRA).	Jennifer Leyva (b) (4) (b) (4)	13 Apr 2021 21:06:18
User opened query 'Per source, this ConMed is not recorded as used for Prophylaxis. Please verify and update EDC/source accordingly.' (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:32:45
DataPoint Un-verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:32:11
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:32:08
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:38:27

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 14:54:12
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:32:48
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'nutritional supplement'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:38:27

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 14:54:12
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:32:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '1000'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:38:27

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 14:54:12
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:32:53
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'mg (mg)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:38:27

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 14:54:12
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:32:56
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:38:27

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 14:54:12
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:32:57
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'once daily (QD)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:38:27

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 14:54:12
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:32:59
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:38:27

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 14:54:12
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:33:01
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Oral (ORAL)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:38:27

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 14:54:12
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:33:08
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:38:27

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 14:54:12
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:33:10
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Aug 2020 08:28:54
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'this is current medication.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:38:33
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 01:38:27
User entered 'un UNK 2015'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:38:27

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US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 14:54:12
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:33:12
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:38:27

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 14:54:12
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:33:14
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:38:27

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 14:54:12
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:33:16
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:38:27

FDA-CBER-2022-1614-0005568

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 14:54:12
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:33:17
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:38:27

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 14:54:12
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '1'	(b) (4), (b) (6) System	11 Aug 2020 01:38:27

FDA-CBER-2022-1614-0005570

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '1'	System	11 Aug 2020 01:38:27

FDA-CBER-2022-1614-0005571

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '804 (804)'	System	11 Aug 2020 01:38:27

FDA-CBER-2022-1614-0005572

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:54:12

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:33:24
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: HYDROCODONE/APAP - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:41:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:41:18
Data point term sent to Coder	System	11 Aug 2020 01:40:05
User entered 'hydrocodone/apap'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:39:37

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 14:54:12
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:33:30
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:39:37

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:54:12

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:33:32
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
Query 'Per DM CLR: Please update the indication and provide the location and laterality of the OSTEOARTHRITIS (e.g. knee; bilateral, left, right). Review and update indication and ensure to update MH eCRF as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	30 Sep 2020 10:01:58
User opened query 'Per DM CLR: Please update the indication and provide the location and laterality of the OSTEOARTHRITIS (e.g. knee; bilateral, left, right). Review and update indication and ensure to update MH eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	06 Sep 2020 08:00:29
User entered 'osteoarthritis'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:39:37

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 14:54:12
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:33:34
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '10/325'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:39:37

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 14:54:12
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:33:36
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'mg (mg)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:39:37

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 14:54:12
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:33:38
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:39:37

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 14:54:12
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:33:39
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'four times daily (QID)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:39:37

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 14:54:12
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:33:41
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:39:37

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 14:54:12
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:33:43
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Oral (ORAL)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:39:37

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 14:54:12
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:33:44
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:39:37

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 14:54:12
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 16:35:02
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 22:23:02
User closed query 'Per source, ConMed Start Date is recorded as, Un/Unk/2000. Please verify with source and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 22:23:00
Query 'Per source, ConMed Start Date is recorded as, Un/Unk/2000. Please verify with source and update EDC accordingly.' answered with 'Updated' (Site from CRA).	Jennifer Leyva (b) (4) (b) (4)	13 Apr 2021 21:07:32
Signature has been broken.	Jennifer Leyva (b) (4) (b) (4)	13 Apr 2021 21:07:12
User entered 'UN UNK 2000' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	13 Apr 2021 21:07:12
User opened query 'Per source, ConMed Start Date is recorded as, Un/Unk/2000. Please verify with source and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:34:15
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	01 Oct 2020 07:07:05
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' answered with 'updated' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	30 Sep 2020 22:58:12
User entered 'UN UNK 2010' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	30 Sep 2020 22:58:07
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	06 Sep 2020 08:01:52
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Aug 2020 08:29:10

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:54:12

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'this is current medication.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:39:42
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 01:39:37
User entered 'un UNK 2000'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:39:37

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 14:54:12
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:34:16
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:39:37

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 14:54:12
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:34:19
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:39:37

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 14:54:12
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:34:21
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:39:37

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 14:54:12
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:34:23
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:39:37

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 14:54:12
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '4'	System	11 Aug 2020 01:39:37

FDA-CBER-2022-1614-0005589

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '1'	System	11 Aug 2020 01:39:37

FDA-CBER-2022-1614-0005590

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (10)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '804 (804)'	(b) (4), (b) (6) System	11 Aug 2020 01:39:37

FDA-CBER-2022-1614-0005591

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:54:12

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:34:29
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: XANTHINES, PRODUCT: DIPROPHYLLINE, PRODUCTSYNONYM: ASTELIN [DIPROPHYLLINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:28:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:28:49
Data point term sent to Coder	System	11 Aug 2020 01:41:06
User entered 'astelin'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:40:32

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 14:54:12
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:34:31
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:40:32

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 14:54:12
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:34:33
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'emphysema'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:40:32

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 14:54:12
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:34:35
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '137'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:40:32

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 14:54:12
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:34:38
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'ug (ug)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:40:32

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 14:54:12
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:34:40
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:40:32

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:54:12

Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:34:43
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User closed query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	01 Oct 2020 07:07:23
Query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' answered with 'Correct as entered. Med can be used on as needed basis' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	30 Sep 2020 22:58:31
User opened query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	06 Sep 2020 08:02:55
User entered 'as needed (PRN)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:40:32

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 14:54:12
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:34:44
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:40:32

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 14:54:12
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:34:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:40:32

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 14:54:12
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:34:54
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:40:32

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:54:12

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 16:35:02
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 22:23:23
User closed query 'Per source, Start Date for ConMed Start Date is recorded as, Un/Unk/2015. Please verify and update EDC/source accordingly.' (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 22:23:21
Query 'Per source, Start Date for ConMed Start Date is recorded as, Un/Unk/2015. Please verify and update EDC/source accordingly.' answered with 'Updated' (Site from CRA).	Jennifer Leyva (b) (4) (b) (4)	13 Apr 2021 21:11:11
Signature has been broken.	Jennifer Leyva (b) (4) (b) (4)	13 Apr 2021 21:09:47
User entered 'UN UNK 2015' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	13 Apr 2021 21:09:47
User opened query 'Per source, Start Date for ConMed Start Date is recorded as, Un/Unk/2015. Please verify and update EDC/source accordingly.' (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:36:12
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	01 Oct 2020 07:08:16
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' answered with 'updated' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	30 Sep 2020 22:58:48
User entered 'UN UNK 2019' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	30 Sep 2020 22:58:43
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	06 Sep 2020 08:03:32

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:54:12

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Aug 2020 08:29:21
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'this is current medication.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:40:37
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 01:40:32
User entered 'un UNK 2015'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:40:32

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 14:54:12
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:36:13
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:40:32

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 14:54:12
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:36:16
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:40:32

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 14:54:12
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:36:18
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:40:32

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 14:54:12
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:36:22
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:40:32

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 14:54:12
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	11 Aug 2020 01:40:32

FDA-CBER-2022-1614-0005608

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	11 Aug 2020 01:40:32

FDA-CBER-2022-1614-0005609

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (11)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	11 Aug 2020 01:40:32

FDA-CBER-2022-1614-0005610

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:54:12

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:36:27
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: DIPHENYLMETHANE DERIVATIVES, PRODUCT: HYDROXYZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:43:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:43:20
Data point term sent to Coder	System	11 Aug 2020 01:42:07
User entered 'hydroxyzine'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:41:34

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 14:54:12
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:36:30
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:41:34

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 14:54:12
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:36:31
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'insomnia'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:41:34

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 14:54:12
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:36:33
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '50'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:41:34

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 14:54:12
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:36:34
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'mg (mg)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:41:34

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 14:54:12
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:36:35
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:41:34

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 14:54:12
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:36:37
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'once daily (QD)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:41:34

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 14:54:12
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:36:39
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:41:34

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 14:54:12
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:36:41
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Oral (ORAL)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:41:34

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 14:54:12
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:36:43
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:41:34

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:54:12

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:36:46
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Aug 2020 08:29:28
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'this is current medication.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:41:38
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 01:41:34
User entered 'un UNK 2018'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:41:34

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 14:54:12
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:36:48
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:41:34

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 14:54:12
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:36:50
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:41:34

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 14:54:12
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:36:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:41:34

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 14:54:12
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:36:54
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:41:34

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 14:54:12
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '1'	(b) (4), (b) (6) System	11 Aug 2020 01:41:34

FDA-CBER-2022-1614-0005626

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '1'	System	11 Aug 2020 01:41:34

FDA-CBER-2022-1614-0005627

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (12)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '804 (804)'	(b) (4), (b) (6) System	11 Aug 2020 01:41:34

FDA-CBER-2022-1614-0005628

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:54:12

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:36:59
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON BIVALENT, ORAL PREPARATIONS, PRODUCT: IRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 13:16:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 13:16:16
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, PRODUCT: IRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:44:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:44:21
Data point term sent to Coder	System	11 Aug 2020 01:43:07
User entered 'IRON' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:43:01
User entered 'jiron'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:42:31

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 14:54:12
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	16 Apr 2021 16:22:22
User closed query 'Per source, this ConMed is not recorded as Prophylaxis. Please verify and update EDC/source accordingly.' (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	16 Apr 2021 16:22:20
Query 'Per source, this ConMed is not recorded as Prophylaxis. Please verify and update EDC/source accordingly.' answered with 'Source has been updated' (Site from CRA).	Jennifer Leyva (b) (4) (b) (4)	13 Apr 2021 21:11:54
User opened query 'Per source, this ConMed is not recorded as Prophylaxis. Please verify and update EDC/source accordingly.' (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:37:28
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User closed query 'Per DM CLR: Prophylaxis = No. However, kindly review and confirm if the response should be updated to 'Yes' instead since this medication is used as a prophylaxis/supplement.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	15 Oct 2020 06:34:36
Query 'Per DM CLR: Prophylaxis = No. However, kindly review and confirm if the response should be updated to 'Yes' instead since this medication is used as a prophylaxis/supplement.' answered with 'updated' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	30 Sep 2020 22:59:10
User entered 'Yes (Y)' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	30 Sep 2020 22:59:04
User opened query 'Per DM CLR: Prophylaxis = No. However, kindly review and confirm if the response should be updated to 'Yes' instead since this medication is used as a prophylaxis/supplement.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	04 Sep 2020 13:23:49
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:42:31

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 14:54:12
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:37:34
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'nutritional supplement'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:42:31

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:54:12

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:37:36
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	01 Oct 2020 07:09:18
Query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'UNK. Confirmed with pt, dosage not known.' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	30 Sep 2020 22:59:31
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	04 Sep 2020 13:24:03
User entered '2'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:42:31

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 14:54:12
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:37:38
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'tablet (TABLET)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:42:31

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 14:54:12
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:37:41
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:42:31

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 14:54:12
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:37:44
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'once daily (QD)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:42:31

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 14:54:12
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:37:46
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:42:31

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 14:54:12
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:37:48
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Oral (ORAL)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:42:31

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 14:54:12
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:37:49
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:42:31

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 14:54:12
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:37:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Aug 2020 08:29:34
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'this is current medication.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:42:36
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 01:42:31
User entered 'un UNK 2017'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:42:31

FDA-CBER-2022-1614-0005639

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 14:54:12
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:37:53
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:42:31

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 14:54:12
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:37:54
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:42:31

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 14:54:12
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:37:55
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:42:31

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 14:54:12
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:37:57
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:42:31

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 14:54:12
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '1'	System	11 Aug 2020 01:42:31

FDA-CBER-2022-1614-0005644

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '1'	System	11 Aug 2020 01:42:31

FDA-CBER-2022-1614-0005645

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (13)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '804 (804)'	(b) (4), (b) (6) System	11 Aug 2020 01:42:31

FDA-CBER-2022-1614-0005646

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:54:12

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:38:01
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: LAMOTRIGINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:45:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:45:22
Data point term sent to Coder	System	11 Aug 2020 01:44:09
User entered 'lamotrigine'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:44:04

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 14:54:12
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:38:03
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:44:04

FDA-CBER-2022-1614-0005648

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:54:12

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:38:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
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) (b) (4), (b) (6) (b) (4), (b) (6)	06 Oct 2020 08:41:42
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 'MEDICAL HISTORY UPDATED' (Site from DM).	Lamar Box (b) (4) (b) (4)	03 Oct 2020 01:23:03
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) (b) (4), (b) (6)	06 Sep 2020 12:45:00
User entered 'bipolar disorder'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:44:04

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 14:54:12
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:38:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '25'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:44:04

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 14:54:12
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:38:10
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'mg (mg)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:44:04

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 14:54:12
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:38:13
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:44:04

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 14:54:12
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:38:14
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'once daily (QD)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:44:04

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 14:54:12
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:38:16
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:44:04

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 14:54:12
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:38:18
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Oral (ORAL)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:44:04

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 14:54:12
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:38:21
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:44:04

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 14:54:12
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:38:23
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Aug 2020 08:29:41
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'this is current medication.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:44:08
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 01:44:04
User entered 'un UNK 2018'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:44:04

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 14:54:12
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:38:25
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:44:04

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 14:54:12
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:38:26
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:44:04

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US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 14:54:12
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:38:28
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:44:04

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 14:54:12
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:38:30
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:44:04

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 14:54:12
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '1'	System	11 Aug 2020 01:44:04

FDA-CBER-2022-1614-0005662

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '1'	System	11 Aug 2020 01:44:04

FDA-CBER-2022-1614-0005663

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (14)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '804 (804)'	System	11 Aug 2020 01:44:04

FDA-CBER-2022-1614-0005664

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:54:12

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:38:35
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:47:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:47:24
Data point term sent to Coder	System	11 Aug 2020 01:46:10
User entered 'levothyroxine'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:45:17

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 14:54:12
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:38:37
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:45:17

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 14:54:12
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:38:38
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'hypothyroidism'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:45:17

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 14:54:12
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:38:40
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '100'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:45:17

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 14:54:12
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 16:35:02
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 22:24:04
User closed query 'Per source, Dose unit is recorded as, mg. Please verify and update EDC/source accordingly.' (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 22:24:03
Query 'Per source, Dose unit is recorded as, mg. Please verify and update EDC/source accordingly.' answered with 'Updated' (Site from CRA).	Jennifer Leyva (b) (4) (b) (4)	13 Apr 2021 21:13:00
Signature has been broken.	Jennifer Leyva (b) (4) (b) (4)	13 Apr 2021 21:12:42
User entered 'mg (mg)' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	13 Apr 2021 21:12:42
User opened query 'Per source, Dose unit is recorded as, mg. Please verify and update EDC/source accordingly.' (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:39:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. Otherwise, confirm if the Dose Unit should be updated to 'ug' instead so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	01 Oct 2020 07:09:55
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. Otherwise, confirm if the Dose Unit should be updated to 'ug' instead so there is an appropriate match. Update eCRF as appropriate.' answered with 'updated' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	30 Sep 2020 23:00:28
User entered 'ug (ug)' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	30 Sep 2020 23:00:25

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:54:12

Dose unit

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. Otherwise, confirm if the Dose Unit should be updated to 'ug' instead so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	06 Sep 2020 12:45:47
User entered 'mg (mg)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:45:17

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 14:54:12
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:39:10
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:45:17

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 14:54:12
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:39:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'once daily (QD)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:45:17

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 14:54:12
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:39:13
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:45:17

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 14:54:12
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:39:15
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Oral (ORAL)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:45:17

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 14:54:12
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:39:17
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:45:17

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 14:54:12
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:39:20
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Aug 2020 08:30:09
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'this is current medication.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:45:21
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 01:45:17
User entered 'un UNK 2018'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:45:17

FDA-CBER-2022-1614-0005676

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 14:54:12
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:39:22
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:45:17

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 14:54:12
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:39:24
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:45:17

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 14:54:12
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:39:26
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:45:17

FDA-CBER-2022-1614-0005679

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 14:54:12
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:39:28
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:45:17

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 14:54:12
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '1'	System	11 Aug 2020 01:45:17

FDA-CBER-2022-1614-0005681

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '1'	System	11 Aug 2020 01:45:17

FDA-CBER-2022-1614-0005682

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (15)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '804 (804)'	(b) (4), (b) (6) System	11 Aug 2020 01:45:17

FDA-CBER-2022-1614-0005683

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:54:12

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:39:32
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
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)	11 Aug 2020 01:48:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:48:26
Data point term sent to Coder	System	11 Aug 2020 01:47:11
User entered 'metoprolol'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:46:11

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 14:54:12
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:39:34
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:46:11

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 14:54:12
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:39:36
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'hypertension'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:46:11

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 14:54:12
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 16:35:02
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 22:24:14
User closed query 'Per source, dose per administration is recorded as, 20 mg. Please verify and update EDC/source accordingly.' (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 22:24:12
Query 'Per source, dose per administration is recorded as, 20 mg. Please verify and update EDC/source accordingly.' answered with 'Updated' (Site from CRA).	Jennifer Leyva (b) (4) (b) (4)	13 Apr 2021 21:14:04
Signature has been broken.	Jennifer Leyva (b) (4) (b) (4)	13 Apr 2021 21:13:48
User entered '20' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	13 Apr 2021 21:13:48
User opened query 'Per source, dose per administration is recorded as, 20 mg. Please verify and update EDC/source accordingly.' (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:40:07
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	01 Oct 2020 07:10:02
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'updated' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	30 Sep 2020 23:01:38
User entered '25' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	30 Sep 2020 23:01:34
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	06 Sep 2020 08:04:31
User entered '20'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:46:11

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 14:54:12
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:40:10
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'mg (mg)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:46:11

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 14:54:12
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:40:12
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:46:11

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US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 14:54:12
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:40:14
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'once daily (QD)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:46:11

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 14:54:12
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:40:17
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:46:11

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 14:54:12
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:40:19
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Oral (ORAL)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:46:11

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 14:54:12
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:40:21
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:46:11

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 14:54:12
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 16:35:02
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 22:24:18
User closed query 'Per source, ConMed Start Date is recorded as, Un/Unk/2018. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 22:24:17
Query 'Per source, ConMed Start Date is recorded as, Un/Unk/2018. Please verify and update EDC accordingly.' answered with 'Updated' (Site from CRA).	Jennifer Leyva (b) (4) (b) (4)	13 Apr 2021 21:14:17
Signature has been broken.	Jennifer Leyva (b) (4) (b) (4)	13 Apr 2021 21:13:48
User entered 'UN UNK 2018' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	13 Apr 2021 21:13:48
User opened query 'Per source, ConMed Start Date is recorded as, Un/Unk/2018. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:40:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	01 Oct 2020 07:10:31
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' answered with 'updated' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	30 Sep 2020 23:01:41
User entered 'UN UNK 2019' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	30 Sep 2020 23:01:34
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	06 Sep 2020 08:05:45
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Aug 2020 08:30:15

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US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:54:12

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'this is current medication.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:46:15
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 01:46:11
User entered 'un UNK 2018'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:46:11

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 14:54:12
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:40:54
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:46:11

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 14:54:12
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:40:56
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:46:11

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 14:54:12
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:40:57
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:46:11

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US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 14:54:12
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:40:59
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:46:11

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 14:54:12
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '1'	System	11 Aug 2020 01:46:11

FDA-CBER-2022-1614-0005700

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '1'	(b) (4), (b) (6) System	11 Aug 2020 01:46:11

FDA-CBER-2022-1614-0005701

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (16)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '804 (804)'	(b) (4), (b) (6) System	11 Aug 2020 01:46:11

FDA-CBER-2022-1614-0005702

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 14:54:12
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:41:12
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Oct 2020 01:26:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Oct 2020 01:26:54
Data point term sent to Coder	System	03 Oct 2020 01:26:10
Coding entries removed.	Lamar Box (b) (4) (b) (4)	03 Oct 2020 01:26:05
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 14:20:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 14:20:08
Data point term sent to Coder	System	11 Aug 2020 01:47:13
User entered 'montelukast'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:47:09

FDA-CBER-2022-1614-0005703

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 14:54:12
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:41:14
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:47:09

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 14:54:12
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:41:17
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	15 Oct 2020 06:40:53
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'DATA CORRECTED' (Site from DM).	Lamar Box (b) (4) (b) (4)	03 Oct 2020 01:26:13
User entered 'SEASONAL ALLERGIES' reason for change: Data Entry Error	Lamar Box (b) (4) (b) (4)	03 Oct 2020 01:26:05
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	06 Sep 2020 08:07:27
User entered 'hypercholesterolemia'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:47:09

FDA-CBER-2022-1614-0005705

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 14:54:12
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:41:18
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '20'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:47:09

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 14:54:12
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:41:20
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'mg (mg)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:47:09

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 14:54:12
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:41:22
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:47:09

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 14:54:12
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:41:23
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'once daily (QD)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:47:09

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 14:54:12
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:41:33
DataPoint Un-verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:41:31
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:41:25
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:47:09

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 14:54:12
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:41:34
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Oral (ORAL)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:47:09

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 14:54:12
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:41:36
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:47:09

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 14:54:12
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:41:38
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Aug 2020 08:30:23
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'this is current medication.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:47:13
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 01:47:09
User entered 'un UNK 2017'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:47:09

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 14:54:12
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:41:39
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:47:09

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 14:54:12
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:41:42
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:47:09

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 14:54:12
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:41:45
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:47:09

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 14:54:12
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:41:47
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:47:09

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 14:54:12
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '1'	(b) (4), (b) (6) System	11 Aug 2020 01:47:09

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US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '1'	System	11 Aug 2020 01:47:09

FDA-CBER-2022-1614-0005719

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (17)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '804 (804)'	(b) (4), (b) (6) System	11 Aug 2020 01:47:09

FDA-CBER-2022-1614-0005720

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:54:12

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:41:51
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: OTHER ANTIMIGRAINE PREPARATIONS, PRODUCT: TOPIRAMATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 21:06:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 21:06:14
Data point term sent to Coder	System	11 Aug 2020 01:48:13
User entered 'topiramate'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:48:09

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 14:54:12
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:41:55
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:48:09

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 14:54:12
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:41:57
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'fibromyalgia'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:48:09

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:54:12

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	15 Apr 2021 16:35:02
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 22:24:35
User closed query 'Per source, dose per administration is recorded as, 100 mg. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	14 Apr 2021 22:24:33
Query 'Per source, dose per administration is recorded as, 100 mg. Please verify and update EDC accordingly.' answered with 'Updated' (Site from CRA).	Jennifer Leyva (b) (4) (b) (4)	13 Apr 2021 21:15:29
Signature has been broken.	Jennifer Leyva (b) (4) (b) (4)	13 Apr 2021 21:15:09
User entered '100' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	13 Apr 2021 21:15:09
User opened query 'Per source, dose per administration is recorded as, 100 mg. Please verify and update EDC accordingly.' (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:42:26
DataPoint Un-verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:42:00
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:41:59
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '200'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:48:09

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 14:54:12
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:42:32
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'mg (mg)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:48:09

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 14:54:12
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:42:35
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:48:09

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 14:54:12
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:42:37
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'twice daily (BID)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:48:09

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 14:54:12
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:42:38
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:48:09

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 14:54:12
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:42:40
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Oral (ORAL)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:48:09

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 14:54:12
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:42:41
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:48:09

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 14:54:12
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:42:43
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Aug 2020 08:30:30
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'this is current medication.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:48:13
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 01:48:09
User entered 'un UNK 2017'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:48:09

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 14:54:12
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:42:44
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:48:09

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 14:54:12
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:42:46
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:48:09

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 14:54:12
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:42:48
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:48:09

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 14:54:12
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:42:50
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:48:09

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 14:54:12
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '2'	System	11 Aug 2020 01:48:09

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US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '1'	System	11 Aug 2020 01:48:09

FDA-CBER-2022-1614-0005737

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (18)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '804 (804)'	System	11 Aug 2020 01:48:09

FDA-CBER-2022-1614-0005738

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:54:12

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:42:56
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: VORTIOXETINE HYDROBROMIDE, PRODUCTSYNONYM: TRINTELLIX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:50:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 01:50:16
Data point term sent to Coder	System	11 Aug 2020 01:49:14
User entered 'trintellix'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:48:56

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 14:54:12
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:42:58
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:48:56

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 14:54:12
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:43:01
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'depression'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:48:56

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 14:54:12
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:43:04
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '20'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:48:56

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 14:54:12
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:43:06
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'mg (mg)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:48:56

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 14:54:12
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:43:08
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:48:56

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 14:54:12
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:43:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'once daily (QD)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:48:56

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 14:54:12
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:43:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:48:56

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 14:54:12
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:43:12
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Oral (ORAL)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:48:56

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 14:54:12
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:43:14
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:48:56

FDA-CBER-2022-1614-0005748

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 14:54:12
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:43:16
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Aug 2020 08:30:38
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'this is current medication.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:48:59
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 01:48:56
User entered 'un UNK 2019'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:48:56

FDA-CBER-2022-1614-0005749

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 14:54:12
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:43:17
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:48:56

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 14:54:12
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:43:19
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:48:56

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 14:54:12
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:43:21
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:48:56

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 14:54:12
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:43:23
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:48:56

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 14:54:12
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '1'	System	11 Aug 2020 01:48:56

FDA-CBER-2022-1614-0005754

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '1'	System	11 Aug 2020 01:48:56

FDA-CBER-2022-1614-0005755

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (19)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '804 (804)'	(b) (4), (b) (6) System	11 Aug 2020 01:48:56

FDA-CBER-2022-1614-0005756

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:54:12

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:45:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, ATC: INTESTINAL ANTIINFECTIVES, ATC: ANTIBIOTICS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 00:21:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 00:21:24
Data point term sent to Coder	System	13 Oct 2020 21:46:01
User entered 'vancomycin'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:45:09

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 14:54:12
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:45:38
User entered 'No (N)'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:45:09

FDA-CBER-2022-1614-0005758

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 14:54:12
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:45:43
User entered 'C-Diff'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:45:09

FDA-CBER-2022-1614-0005759

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 14:54:12
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:45:46
User entered '125'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:45:09

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 14:54:12
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:45:48
User entered 'mg (mg)'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:45:09

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 14:54:12
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:45:50
User entered empty.	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:45:09

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 14:54:12
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:45:51
User entered 'four times daily (QID)'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:45:09

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 14:54:12
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:45:53
User entered empty.	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:45:09

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 14:54:12
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:45:54
User entered 'Oral (ORAL)'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:45:09

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 14:54:12
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:45:56
User entered empty.	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:45:09

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 14:54:12
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:45:58
User entered '29 Sep 2020'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:45:09

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 14:54:12
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:46:00
User entered '0'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:45:09

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 14:54:12
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:43:31
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Un-verified.	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:49:00
User entered 'No (N)' reason for change: New Information	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:49:00
User closed query 'Per DM CLR: Please note, the corresponding AE has resolved. However, this medication is still ongoing. Please reconcile AE/CM dates and update if appropriate. Otherwise, clarify continued use after AE resolution.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	23 Nov 2020 08:39:26
Query 'Per DM CLR: Please note, the corresponding AE has resolved. However, this medication is still ongoing. Please reconcile AE/CM dates and update if appropriate. Otherwise, clarify continued use after AE resolution.' answered with 'Correct as entered. CM is ongoing for prevention' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	20 Nov 2020 13:50:02
User opened query 'Per DM CLR: Please note, the corresponding AE has resolved. However, this medication is still ongoing. Please reconcile AE/CM dates and update if appropriate. Otherwise, clarify continued use after AE resolution.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 07:12:02
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:46:02
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:45:09

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 14:54:12
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:43:33
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Un-verified.	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:49:00
User entered '22 Oct 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:49:00
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:46:05
User entered empty.	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:45:09

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 14:54:12
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:46:08
User entered 'No (N)'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:45:09

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 14:54:12
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '4'	System	13 Oct 2020 21:45:09

FDA-CBER-2022-1614-0005772

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '1'	System	13 Oct 2020 21:45:09

FDA-CBER-2022-1614-0005773

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (20)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '804 (804)'	System	13 Oct 2020 21:45:09

FDA-CBER-2022-1614-0005774

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 14:54:12
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:46:52
Query 'Please add medications taken for SAEs to source ConMed logs. ' canceled (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:45:15
User opened query 'Please add medications taken for SAEs to source ConMed logs. ' (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:45:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: SYNTHETIC ANTICHOLINERGICS, ESTERS WITH TERTIARY AMINO GROUP, PRODUCT: DICYCLOVERINE, PRODUCTSYNONYM: DICYCLOMINE [DICYCLOVERINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 20:48:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Oct 2020 20:48:39
Data point term sent to Coder	System	26 Oct 2020 12:31:26
Coding entries removed.	Jennifer Leyva (b) (4) (b) (4)	26 Oct 2020 12:31:09
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: SYNTHETIC ANTICHOLINERGICS, ESTERS WITH TERTIARY AMINO GROUP, PRODUCT: DICYCLOVERINE, PRODUCTSYNONYM: DICYCLOMINE [DICYCLOVERINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 23:59:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 23:59:19
Data point term sent to Coder	System	13 Oct 2020 21:47:02
User entered 'dicyclomine'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:46:09

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 14:54:12
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:43:40
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User closed query 'Per DM CLR: Prophlaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Feb 2021 10:28:58
Query 'Per DM CLR: Prophlaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' answered with 'Updated' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	28 Jan 2021 20:15:12
DataPoint Un-verified.	Jennifer Leyva (b) (4) (b) (4)	28 Jan 2021 20:15:07
User entered 'No (N)' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	28 Jan 2021 20:15:07
User opened query 'Per DM CLR: Prophlaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	28 Jan 2021 09:09:47
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:46:54
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:46:09

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:54:12

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	30 Oct 2020 16:02:14
User closed query 'Source still indicates infection prophylaxis. Please ensure source and eCRF match. ' (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	30 Oct 2020 16:02:13
Query 'Source still indicates infection prophylaxis. Please ensure source and eCRF match. ' answered with 'source corrected' (Site from CRA).	Jennifer Leyva (b) (4) (b) (4)	29 Oct 2020 20:18:38
User opened query 'Source still indicates infection prophylaxis. Please ensure source and eCRF match. ' (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:46:50
User entered 'Colitis (AE #1)' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	26 Oct 2020 12:31:09
User entered 'infection prophylaxis'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:46:09

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 14:54:12
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:47:00
User entered '20'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:46:09

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 14:54:12
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:47:02
User entered 'mg (mg)'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:46:09

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US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 14:54:12
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:47:04
User entered empty.	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:46:09

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 14:54:12
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:47:05
User entered 'four times daily (QID)'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:46:09

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 14:54:12
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:47:06
User entered empty.	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:46:09

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 14:54:12
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:47:09
User entered 'Oral (ORAL)'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:46:09

FDA-CBER-2022-1614-0005783

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 14:54:12
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:47:10
User entered empty.	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:46:09

FDA-CBER-2022-1614-0005784

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 14:54:12
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:47:12
User entered '29 Sep 2020'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:46:09

FDA-CBER-2022-1614-0005785

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 14:54:12
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:47:13
User entered '0'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:46:09

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 14:54:12
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:43:47
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Un-verified.	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:49:19
User entered 'No (N)' reason for change: New Information	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:49:19
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:47:15
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:46:09

FDA-CBER-2022-1614-0005787

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:54:12

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:43:48
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User closed query 'Per DM CLR: Con Med stop date is after the stop date of the AE. It is not expected that this treatment would continue past the AE. Please review and reconcile Con Med and AE stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 11:21:07
Query 'Per DM CLR: Con Med stop date is after the stop date of the AE. It is not expected that this treatment would continue past the AE. Please review and reconcile Con Med and AE stop dates as appropriate. ' answered with 'Correct as entered. Patient continued taking med after AE ended.' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	07 Dec 2020 17:17:42
User opened query 'Per DM CLR: Con Med stop date is after the stop date of the AE. It is not expected that this treatment would continue past the AE. Please review and reconcile Con Med and AE stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 18:16:26
DataPoint Un-verified.	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:49:19
User entered '12 Oct 2020' reason for change: New Information	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:49:19
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:47:17
User entered empty.	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:46:09

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 14:54:12
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:47:18
User entered 'No (N)'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:46:09

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 14:54:12
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '4'	System	13 Oct 2020 21:46:09

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US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '1'	System	13 Oct 2020 21:46:09

FDA-CBER-2022-1614-0005791

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (21)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '804 (804)'	(b) (4), (b) (6) System	13 Oct 2020 21:46:09

FDA-CBER-2022-1614-0005792

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:54:12

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:47:26
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ONDASETRON [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 05:33:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 05:33:28
Data point term sent to Coder	System	13 Oct 2020 21:48:04
User entered 'ondasetron'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:47:19

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 14:54:12
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:47:29
User entered 'No (N)'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:47:19

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US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:54:12

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 09:38:25
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' answered with 'Medication related from hosptialization' (Site from DM).	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:49:26
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 19:09:21
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:47:32
User entered 'nausea'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:47:19

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 14:54:12
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:47:34
User entered '4'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:47:19

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 14:54:12
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:47:36
User entered 'mg (mg)'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:47:19

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 14:54:12
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:47:37
User entered empty.	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:47:19

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US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 14:54:12
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:47:38
User entered 'other (OTHER)'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:47:19

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 14:54:12
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:47:41
User entered 'Q6H/PRN'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:47:19

FDA-CBER-2022-1614-0005800

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 14:54:12
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:47:43
User entered 'Oral (ORAL)'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:47:19

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 14:54:12
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:47:44
User entered empty.	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:47:19

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 14:54:12
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:47:47
User entered '28 Sep 2020'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:47:19

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 14:54:12
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:47:48
User entered '0'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:47:19

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 14:54:12
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:47:50
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:47:19

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 14:54:12
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:47:52
User entered empty.	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:47:19

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 14:54:12
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:47:54
User entered 'No (N)'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:47:19

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 14:54:12
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	13 Oct 2020 21:47:19

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US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	13 Oct 2020 21:47:19

FDA-CBER-2022-1614-0005809

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	13 Oct 2020 21:47:19

FDA-CBER-2022-1614-0005810

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:54:12

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:47:59
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: ESTERS OF AMINOBENZOIC ACID, PRODUCT: BENZOCAINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 04:51:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 04:51:26
Data point term sent to Coder	System	13 Oct 2020 21:49:05
User entered 'benzoccine 20%'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:48:59

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 14:54:12
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:48:01
User entered 'No (N)'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:48:59

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:54:12

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 09:38:36
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' answered with 'Due to Hospitalization' (Site from DM).	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:49:51
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 19:10:18
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:48:03
User entered 'cracked tongue , fever blister'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:48:59

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 14:54:12
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:48:06
User entered '1'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:48:59

FDA-CBER-2022-1614-0005814

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 14:54:12
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4) (b) (4), (b) (6)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:48:07
User entered 'Other (OTHER)'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:48:59

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 14:54:12
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:48:08
User entered 'application'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:48:59

FDA-CBER-2022-1614-0005816

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 14:54:12
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:48:12
User entered 'as needed (PRN)'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:48:59

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 14:54:12
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:48:15
User entered empty.	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:48:59

FDA-CBER-2022-1614-0005818

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 14:54:12
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:48:17
User entered 'Topical (TOPICAL)'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:48:59

FDA-CBER-2022-1614-0005819

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 14:54:12
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:48:18
User entered empty.	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:48:59

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 14:54:12
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:48:20
User entered '10 Oct 2020'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:48:59

FDA-CBER-2022-1614-0005821

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 14:54:12
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:48:22
User entered '0'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:48:59

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 14:54:12
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:48:24
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:48:59

FDA-CBER-2022-1614-0005823

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 14:54:12
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:48:26
User entered empty.	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:48:59

FDA-CBER-2022-1614-0005824

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 14:54:12
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:48:28
User entered 'No (N)'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:48:59

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 14:54:12
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	13 Oct 2020 21:48:59

FDA-CBER-2022-1614-0005826

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	13 Oct 2020 21:48:59

FDA-CBER-2022-1614-0005827

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (23)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	13 Oct 2020 21:48:59

FDA-CBER-2022-1614-0005828

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:54:12

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:48:35
User coded data point as ATC: DERMATOLOGICALS, ATC: EMOLLIENTS AND PROTECTIVES, ATC: EMOLLIENTS AND PROTECTIVES, ATC: SILICONE PRODUCTS, PRODUCT: DIMETICONE, PRODUCTSYNONYM: DIMETHICONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 00:00:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 00:00:21
Data point term sent to Coder	System	13 Oct 2020 21:54:09
User entered 'dimethicone 1.5%'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:54:03

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 14:54:12
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:48:37
User entered 'No (N)'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:54:03

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:54:12

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 09:38:46
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' answered with 'Due to hospitalization' (Site from DM).	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:50:03
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 19:10:38
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:49:27
User entered 'body aches/weakness'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:54:03

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 14:54:12
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:49:33
User entered '1'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:54:03

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 14:54:12
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:49:35
User entered 'Other (OTHER)'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:54:03

FDA-CBER-2022-1614-0005833

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 14:54:12
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:49:36
User entered 'application'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:54:03

FDA-CBER-2022-1614-0005834

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 14:54:12
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:49:38
User entered 'as needed (PRN)'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:54:03

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 14:54:12
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:49:40
User entered empty.	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:54:03

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 14:54:12
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:49:41
User entered 'Topical (TOPICAL)'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:54:03

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 14:54:12
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:49:43
User entered empty.	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:54:03

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 14:54:12
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:49:44
User entered '10 Oct 2020'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:54:03

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US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 14:54:12
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:49:46
User entered '0'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:54:03

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 14:54:12
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:49:47
User entered 'Yes (Y)'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:54:03

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 14:54:12
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:49:48
User entered empty.	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:54:03

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 14:54:12
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:49:50
User entered 'No (N)'	Katherine Davis (b) (4) (b) (4)	13 Oct 2020 21:54:03

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 14:54:12
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	13 Oct 2020 21:54:03

FDA-CBER-2022-1614-0005844

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	13 Oct 2020 21:54:03

FDA-CBER-2022-1614-0005845

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (24)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	13 Oct 2020 21:54:03

FDA-CBER-2022-1614-0005846

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:54:12

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 21:15:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 21:15:56
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:50:33
Data point term sent to Coder	System	28 Oct 2020 22:07:42
User entered 'Furosemide'	Jennifer Leyva (b) (4) (b) (4)	28 Oct 2020 22:06:43

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 14:54:12
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:50:37
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	28 Oct 2020 22:06:43

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 14:54:12

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	08 Dec 2020 06:18:26
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'No underlying medical condition. Standard practice for bed-ridden patients during hospitalization' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	07 Dec 2020 17:18:42
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 18:16:42
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:50:40
User entered 'Diuretic, from hospitalization'	Jennifer Leyva (b) (4) (b) (4)	28 Oct 2020 22:06:43

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 14:54:12
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:50:43
User entered '40'	Jennifer Leyva (b) (4) (b) (4)	28 Oct 2020 22:06:43

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 14:54:12
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:50:50
User entered 'mg (mg)'	Jennifer Leyva (b) (4) (b) (4)	28 Oct 2020 22:06:43

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 14:54:12
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:50:52
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	28 Oct 2020 22:06:43

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 14:54:12
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:50:56
User entered 'three times daily (TID)'	Jennifer Leyva (b) (4) (b) (4)	28 Oct 2020 22:06:43

FDA-CBER-2022-1614-0005853

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 14:54:12
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:50:58
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	28 Oct 2020 22:06:43

FDA-CBER-2022-1614-0005854

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 14:54:12
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:50:59
User entered 'Subcutaneous (SUBCUTANEOUS)'	Jennifer Leyva (b) (4) (b) (4)	28 Oct 2020 22:06:43

FDA-CBER-2022-1614-0005855

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 14:54:12
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:51:01
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	28 Oct 2020 22:06:43

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 14:54:12
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:51:02
User entered '29 Sep 2020'	Jennifer Leyva (b) (4) (b) (4)	28 Oct 2020 22:06:43

FDA-CBER-2022-1614-0005857

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 14:54:12
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:51:04
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	28 Oct 2020 22:06:43

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 14:54:12
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:51:05
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	28 Oct 2020 22:06:43

FDA-CBER-2022-1614-0005859

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 14:54:12
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:51:07
User entered '01 Oct 2020'	Jennifer Leyva (b) (4) (b) (4)	28 Oct 2020 22:06:43

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 14:54:12
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:51:09
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	28 Oct 2020 22:06:43

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 14:54:12
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '3'	(b) (4), (b) (6) System	28 Oct 2020 22:06:43

FDA-CBER-2022-1614-0005862

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '1'	System	28 Oct 2020 22:06:43

FDA-CBER-2022-1614-0005863

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (25)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '804 (804)'	(b) (4), (b) (6) System	28 Oct 2020 22:06:43

FDA-CBER-2022-1614-0005864

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:54:12

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:16:25
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 20:49:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 20:49:18
Data point term sent to Coder	System	03 Nov 2020 20:54:07
User entered 'Metronidazole'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:53:15

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 09 Jun 2021 14:54:12
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:16:27
User entered 'No (N)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:53:15

FDA-CBER-2022-1614-0005866

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 14:54:12

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User closed query 'Per DM CLR: Please note that there is no AE UTI that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 07:07:30
Query 'Per DM CLR: Please note that there is no AE UTI that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' answered with 'UTI test results were negative.' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	07 Dec 2020 17:19:02
User opened query 'Per DM CLR: Please note that there is no AE UTI that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 18:16:54
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:16:31
User entered 'UTI treatment part of hospitalization'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:53:15

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 09 Jun 2021 14:54:12
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:16:33
User entered '500'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:53:15

FDA-CBER-2022-1614-0005868

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 09 Jun 2021 14:54:12
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:16:35
User entered 'mg (mg)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:53:15

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 09 Jun 2021 14:54:12
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:16:43
User entered empty.	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:53:15

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 09 Jun 2021 14:54:12
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:16:41
User entered 'other (OTHER)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:53:15

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 09 Jun 2021 14:54:12
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:16:45
User entered 'QgH'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:53:15

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US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 09 Jun 2021 14:54:12
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:16:46
User entered 'Oral (ORAL)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:53:15

FDA-CBER-2022-1614-0005873

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 09 Jun 2021 14:54:12
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:16:53
DataPoint Un-verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:16:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:16:48
User entered empty.	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:53:15

FDA-CBER-2022-1614-0005874

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 09 Jun 2021 14:54:12
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:16:52
User entered '29 Sep 2020'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:53:15

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 09 Jun 2021 14:54:12
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:16:55
User entered '0'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:53:15

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 09 Jun 2021 14:54:12
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:16:56
User entered 'No (N)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:53:15

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 09 Jun 2021 14:54:12
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:16:58
User entered '01 Oct 2020'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:53:15

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 09 Jun 2021 14:54:12
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:17:00
User entered 'No (N)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:53:15

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 09 Jun 2021 14:54:12
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	03 Nov 2020 20:53:15

FDA-CBER-2022-1614-0005880

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	03 Nov 2020 20:53:15

FDA-CBER-2022-1614-0005881

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (27)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	03 Nov 2020 20:53:15

FDA-CBER-2022-1614-0005882

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:54:12

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Dec 2020 14:20:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Dec 2020 14:20:48
Data point term sent to Coder	System	07 Dec 2020 17:19:56
Coding entries removed.	Jennifer Leyva (b) (4) (b) (4)	07 Dec 2020 17:19:25
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:17:08
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 05:20:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 05:20:21
Data point term sent to Coder	System	03 Nov 2020 20:55:07
User entered 'Morphine Sulfate'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:54:13

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 09 Jun 2021 14:54:12
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:17:16
User entered 'No (N)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:54:13

FDA-CBER-2022-1614-0005884

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 09 Jun 2021 14:54:12
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:45:20
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User closed query 'Per DM CLR: Please note that there is no AE PAIN IN ABDOMEN that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	08 Dec 2020 06:22:21
Query 'Per DM CLR: Please note that there is no AE PAIN IN ABDOMEN that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' answered with 'Updated' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	07 Dec 2020 17:19:32
DataPoint Un-verified.	Jennifer Leyva (b) (4) (b) (4)	07 Dec 2020 17:19:25
User entered 'PAIN IN ABDOMEN PART OF HOSPITALIZATION (Diagnosed as Colitis)' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	07 Dec 2020 17:19:25
User opened query 'Per DM CLR: Please note that there is no AE PAIN IN ABDOMEN that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 18:17:06
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:17:18
User entered 'Pain in Abdomen part of hospitalization'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:54:13

FDA-CBER-2022-1614-0005885

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 09 Jun 2021 14:54:12
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:17:25
User entered '4'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:54:13

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 14:54:12

Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User closed query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	15 Feb 2021 14:35:12
Query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. ' answered with 'Per records from hospital, correct as entered' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	28 Jan 2021 20:15:39
User opened query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	28 Jan 2021 09:10:27
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:17:31
User entered 'mg (mg)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:54:13

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 09 Jun 2021 14:54:12
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:17:33
User entered empty.	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:54:13

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 09 Jun 2021 14:54:12
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:17:34
User entered 'as needed (PRN)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:54:13

FDA-CBER-2022-1614-0005889

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 09 Jun 2021 14:54:12
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:17:36
User entered empty.	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:54:13

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 09 Jun 2021 14:54:12
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:17:38
User entered 'Oral (ORAL)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:54:13

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 09 Jun 2021 14:54:12
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:17:52
User entered empty.	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:54:13

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 09 Jun 2021 14:54:12
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:17:56
User entered '29 Sep 2020'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:54:13

FDA-CBER-2022-1614-0005893

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 09 Jun 2021 14:54:12
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:17:58
User entered '0'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:54:13

FDA-CBER-2022-1614-0005894

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 09 Jun 2021 14:54:12
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:18:00
User entered 'No (N)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:54:13

FDA-CBER-2022-1614-0005895

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 09 Jun 2021 14:54:12
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:18:02
User entered '13 Oct 2020'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:54:13

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 09 Jun 2021 14:54:12
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:18:15
User entered 'No (N)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:54:13

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 09 Jun 2021 14:54:12
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	03 Nov 2020 20:54:13

FDA-CBER-2022-1614-0005898

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	03 Nov 2020 20:54:13

FDA-CBER-2022-1614-0005899

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (28)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	03 Nov 2020 20:54:13

FDA-CBER-2022-1614-0005900

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 09 Jun 2021 14:54:12
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:31:00
DataPoint Un-verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:30:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:30:43
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 09:03:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 09:03:25
Data point term sent to Coder	System	03 Nov 2020 20:56:10
User entered 'Metronidazole'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:55:28

FDA-CBER-2022-1614-0005901

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 09 Jun 2021 14:54:12
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:30:59
DataPoint Un-verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:30:55
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:30:44
User entered 'No (N)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:55:28

FDA-CBER-2022-1614-0005902

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 14:54:12

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User closed query 'Per DM CLR: Please note that there is no AE UTI that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 07:09:07
Query 'Per DM CLR: Please note that there is no AE UTI that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' answered with 'UTI results negative' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	07 Dec 2020 17:19:44
User opened query 'Per DM CLR: Please note that there is no AE UTI that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 18:17:17
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:31:02
DataPoint Un-verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:30:53
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:30:46
User entered 'UTI treatment pre-emptive part of hospitalization'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:55:28

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 09 Jun 2021 14:54:12
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:31:12
DataPoint Un-verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:30:52
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:30:48
User entered '100'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:55:28

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US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 09 Jun 2021 14:54:12
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:31:14
User entered 'mL (mL)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:55:28

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 09 Jun 2021 14:54:12
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:31:15
User entered empty.	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:55:28

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 09 Jun 2021 14:54:12
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:31:16
User entered 'other (OTHER)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:55:28

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 14:54:12

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:31:19
User closed query 'Per CDM: Please review if the Frequency could be selected from one of the available options in the dropdown list provided (e.g. four times daily). Kindly update as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	12 Nov 2020 08:13:12
Query 'Per CDM: Please review if the Frequency could be selected from one of the available options in the dropdown list provided (e.g. four times daily). Kindly update as appropriate, else clarify.' answered with 'Correct as entered this is how it was prescribed by the physician' (Site from DM).	Pamela Fidler (b) (4) (b) (4) (b) (4)	11 Nov 2020 17:37:51
User opened query 'Per CDM: Please review if the Frequency could be selected from one of the available options in the dropdown list provided (e.g. four times daily). Kindly update as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Nov 2020 14:25:32
User entered 'Q6H'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:55:28

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 09 Jun 2021 14:54:12
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:31:23
User entered 'Intravenous (INTRAVENOUS)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:55:28

FDA-CBER-2022-1614-0005909

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 09 Jun 2021 14:54:12
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:31:25
User entered empty.	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:55:28

FDA-CBER-2022-1614-0005910

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 09 Jun 2021 14:54:12
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:31:26
User entered '29 Sep 2020'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:55:28

FDA-CBER-2022-1614-0005911

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 09 Jun 2021 14:54:12
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:31:28
User entered '0'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:55:28

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 09 Jun 2021 14:54:12
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:31:31
User entered 'No (N)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:55:28

FDA-CBER-2022-1614-0005913

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 09 Jun 2021 14:54:12
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:31:32
User entered '01 Oct 2020'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:55:28

FDA-CBER-2022-1614-0005914

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 09 Jun 2021 14:54:12
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:31:33
User entered 'No (N)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:55:28

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 09 Jun 2021 14:54:12
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	03 Nov 2020 20:55:28

FDA-CBER-2022-1614-0005916

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	03 Nov 2020 20:55:28

FDA-CBER-2022-1614-0005917

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (29)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	03 Nov 2020 20:55:28

FDA-CBER-2022-1614-0005918

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 14:54:12

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:31:40
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE SODIUM SESQUIHYDRATE, PRODUCTSYNONYM: PANTOPRAZOLE SODIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 20:57:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 20:57:33
Data point term sent to Coder	System	03 Nov 2020 20:57:11
User entered 'Pantoprazole Sodium'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:56:16

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (30)
Generated On: 09 Jun 2021 14:54:12
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:31:42
User entered 'No (N)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:56:16

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 14:54:12

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User closed query 'Per DM CLR: Please note that there is no AE GERD that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	08 Dec 2020 06:23:54
Query 'Per DM CLR: Please note that there is no AE GERD that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' answered with 'GERD is part of subject's MH. Different treatment used during hospitalization.' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	07 Dec 2020 17:20:23
User opened query 'Per DM CLR: Please note that there is no AE GERD that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 18:17:29
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:31:45
User entered 'GERD during hospitalization'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:56:16

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (30)
Generated On: 09 Jun 2021 14:54:12
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:31:46
User entered '40'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:56:16

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (30)
Generated On: 09 Jun 2021 14:54:12
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:31:48
User entered 'mg (mg)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:56:16

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (30)
Generated On: 09 Jun 2021 14:54:12
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:31:50
User entered empty.	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:56:16

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (30)
Generated On: 09 Jun 2021 14:54:12
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:31:52
User entered 'once daily (QD)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:56:16

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US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (30)
Generated On: 09 Jun 2021 14:54:12
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:31:53
User entered empty.	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:56:16

FDA-CBER-2022-1614-0005926

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (30)
Generated On: 09 Jun 2021 14:54:12
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:31:56
User entered 'Oral (ORAL)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:56:16

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (30)
Generated On: 09 Jun 2021 14:54:12
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:31:58
User entered empty.	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:56:16

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (30)
Generated On: 09 Jun 2021 14:54:12
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:31:59
User entered '29 Sep 2020'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:56:16

FDA-CBER-2022-1614-0005929

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (30)
Generated On: 09 Jun 2021 14:54:12
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:32:01
User entered '0'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:56:16

FDA-CBER-2022-1614-0005930

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (30)
Generated On: 09 Jun 2021 14:54:12
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:32:03
User entered 'No (N)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:56:16

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (30)
Generated On: 09 Jun 2021 14:54:12
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:32:04
User entered '12 Oct 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 20:30:34
User entered '13 Oct 2020'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:56:16

FDA-CBER-2022-1614-0005932

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (30)
Generated On: 09 Jun 2021 14:54:12
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:32:06
User entered 'No (N)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:56:16

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (30)
Generated On: 09 Jun 2021 14:54:12
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '1'	System	03 Nov 2020 20:56:16

FDA-CBER-2022-1614-0005934

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (30)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '1'	System	03 Nov 2020 20:56:16

FDA-CBER-2022-1614-0005935

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (30)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '804 (804)'	(b) (4), (b) (6) System	03 Nov 2020 20:56:16

FDA-CBER-2022-1614-0005936

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 14:54:12

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:32:11
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE SODIUM SESQUIHYDRATE, PRODUCTSYNONYM: PANTOPRAZOLE SODIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 20:57:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 20:57:33
Data point term sent to Coder	System	03 Nov 2020 20:57:11
User entered 'Pantoprazole Sodium'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:57:05

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (31)
Generated On: 09 Jun 2021 14:54:12
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:32:20
User entered 'No (N)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:57:05

FDA-CBER-2022-1614-0005938

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 14:54:12

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User closed query 'Per DM CLR: Please note that there is no AE GERD that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	08 Dec 2020 06:24:30
Query 'Per DM CLR: Please note that there is no AE GERD that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' answered with 'GERD is part of subject's MH. Treatment used during hospitalization was entered. ' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	07 Dec 2020 17:20:52
User opened query 'Per DM CLR: Please note that there is no AE GERD that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 18:17:55
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:32:22
User entered 'GERD during hospitalization'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:57:05

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (31)
Generated On: 09 Jun 2021 14:54:12
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:32:23
User entered '40'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:57:05

FDA-CBER-2022-1614-0005940

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (31)
Generated On: 09 Jun 2021 14:54:12
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:32:25
User entered 'mg (mg)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:57:05

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (31)
Generated On: 09 Jun 2021 14:54:12
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:32:27
User entered empty.	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:57:05

FDA-CBER-2022-1614-0005942

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (31)
Generated On: 09 Jun 2021 14:54:12
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:32:28
User entered 'once daily (QD)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:57:05

FDA-CBER-2022-1614-0005943

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (31)
Generated On: 09 Jun 2021 14:54:12
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:32:30
User entered empty.	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:57:05

FDA-CBER-2022-1614-0005944

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (31)
Generated On: 09 Jun 2021 14:54:12
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:32:31
User entered 'Intravenous (INTRAVENOUS)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:57:05

FDA-CBER-2022-1614-0005945

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (31)
Generated On: 09 Jun 2021 14:54:12
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:32:32
User entered empty.	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:57:05

FDA-CBER-2022-1614-0005946

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (31)
Generated On: 09 Jun 2021 14:54:12
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:32:34
User entered '29 Sep 2020'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:57:05

FDA-CBER-2022-1614-0005947

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (31)
Generated On: 09 Jun 2021 14:54:12
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:32:35
User entered '0'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:57:05

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (31)
Generated On: 09 Jun 2021 14:54:12
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:32:37
User entered 'No (N)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:57:05

FDA-CBER-2022-1614-0005949

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (31)
Generated On: 09 Jun 2021 14:54:12
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:32:38
User entered '12 Oct 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 20:30:12
User entered '13 Oct 2020'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:57:05

FDA-CBER-2022-1614-0005950

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (31)
Generated On: 09 Jun 2021 14:54:12
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:32:40
User entered 'No (N)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:57:05

FDA-CBER-2022-1614-0005951

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (31)
Generated On: 09 Jun 2021 14:54:12
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '1'	(b) (4), (b) (6) System	03 Nov 2020 20:57:05

FDA-CBER-2022-1614-0005952

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (31)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '1'	System	03 Nov 2020 20:57:05

FDA-CBER-2022-1614-0005953

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (31)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '804 (804)'	(b) (4), (b) (6) System	03 Nov 2020 20:57:05

FDA-CBER-2022-1614-0005954

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 14:54:12

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:20:19
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL, PRODUCTSYNONYM: POLYETHYLENE GLYCOL [MACROGOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 05:24:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 05:24:24
Data point term sent to Coder	System	03 Nov 2020 20:58:12
User entered 'Polyethylene Glycol'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:58:07

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (32)
Generated On: 09 Jun 2021 14:54:12
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:20:21
User entered 'No (N)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:58:07

FDA-CBER-2022-1614-0005956

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (32)
Generated On: 09 Jun 2021 14:54:12
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:20:23
User entered 'Pain in Abdomen dx colitis'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:58:07

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (32)
Generated On: 09 Jun 2021 14:54:12
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:20:25
User entered '17'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:58:07

FDA-CBER-2022-1614-0005958

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (32)
Generated On: 09 Jun 2021 14:54:12
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:20:27
User entered 'g (g)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:58:07

FDA-CBER-2022-1614-0005959

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (32)
Generated On: 09 Jun 2021 14:54:12
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:20:28
User entered empty.	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:58:07

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (32)
Generated On: 09 Jun 2021 14:54:12
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:20:30
User entered 'as needed (PRN)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:58:07

FDA-CBER-2022-1614-0005961

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (32)
Generated On: 09 Jun 2021 14:54:12
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:20:31
User entered empty.	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:58:07

FDA-CBER-2022-1614-0005962

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (32)
Generated On: 09 Jun 2021 14:54:12
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:20:33
User entered 'Oral (ORAL)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:58:07

FDA-CBER-2022-1614-0005963

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (32)
Generated On: 09 Jun 2021 14:54:12
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:20:35
User entered empty.	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:58:07

FDA-CBER-2022-1614-0005964

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (32)
Generated On: 09 Jun 2021 14:54:12
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:20:36
User entered '29 Sep 2020'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:58:07

FDA-CBER-2022-1614-0005965

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (32)
Generated On: 09 Jun 2021 14:54:12
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:20:38
User entered '0'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:58:07

FDA-CBER-2022-1614-0005966

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (32)
Generated On: 09 Jun 2021 14:54:12
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:20:39
User entered 'No (N)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:58:07

FDA-CBER-2022-1614-0005967

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (32)
Generated On: 09 Jun 2021 14:54:12
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:32:45
DataPoint Un-verified.	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 20:31:03
User entered '12 Oct 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 20:31:03
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:20:41
User entered '13 Oct 2020'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:58:07

FDA-CBER-2022-1614-0005968

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (32)
Generated On: 09 Jun 2021 14:54:12
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:20:42
User entered 'No (N)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:58:07

FDA-CBER-2022-1614-0005969

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (32)
Generated On: 09 Jun 2021 14:54:12
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	03 Nov 2020 20:58:07

FDA-CBER-2022-1614-0005970

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (32)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	03 Nov 2020 20:58:07

FDA-CBER-2022-1614-0005971

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (32)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	03 Nov 2020 20:58:07

FDA-CBER-2022-1614-0005972

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 14:54:12

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:20:49
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL HYDROCHLORIDE, PRODUCTSYNONYM: TRAMADOL HCL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 21:00:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 21:00:26
Data point term sent to Coder	System	03 Nov 2020 20:59:14
User entered 'Tramadol HCL'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:58:54

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (33)
Generated On: 09 Jun 2021 14:54:12
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:20:51
User entered 'No (N)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:58:54

FDA-CBER-2022-1614-0005974

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (33)
Generated On: 09 Jun 2021 14:54:12
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:20:52
User entered 'Pain in abdomen dx Colitis during hospitalization'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:58:54

FDA-CBER-2022-1614-0005975

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (33)
Generated On: 09 Jun 2021 14:54:12
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:20:55
User entered '100'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:58:54

FDA-CBER-2022-1614-0005976

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (33)
Generated On: 09 Jun 2021 14:54:12
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:20:56
User entered 'mg (mg)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:58:54

FDA-CBER-2022-1614-0005977

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (33)
Generated On: 09 Jun 2021 14:54:12
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:20:58
User entered empty.	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:58:54

FDA-CBER-2022-1614-0005978

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (33)
Generated On: 09 Jun 2021 14:54:12
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:20:59
User entered 'twice daily (BID)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:58:54

FDA-CBER-2022-1614-0005979

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (33)
Generated On: 09 Jun 2021 14:54:12
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:21:01
User entered empty.	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:58:54

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (33)
Generated On: 09 Jun 2021 14:54:12
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:21:02
User entered 'Oral (ORAL)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:58:54

FDA-CBER-2022-1614-0005981

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (33)
Generated On: 09 Jun 2021 14:54:12
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:21:04
User entered empty.	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:58:54

FDA-CBER-2022-1614-0005982

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (33)
Generated On: 09 Jun 2021 14:54:12
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:21:05
User entered '29 Sep 2020'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:58:54

FDA-CBER-2022-1614-0005983

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (33)
Generated On: 09 Jun 2021 14:54:12
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:21:07
User entered '0'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:58:54

FDA-CBER-2022-1614-0005984

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (33)
Generated On: 09 Jun 2021 14:54:12
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:21:08
User entered 'No (N)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:58:54

FDA-CBER-2022-1614-0005985

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (33)
Generated On: 09 Jun 2021 14:54:12
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:32:50
DataPoint Un-verified.	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 20:31:12
User entered '12 Oct 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 20:31:12
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:21:10
User entered '13 Oct 2020'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:58:54

FDA-CBER-2022-1614-0005986

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (33)
Generated On: 09 Jun 2021 14:54:12
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:21:15
User entered 'No (N)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 20:58:54

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (33)
Generated On: 09 Jun 2021 14:54:12
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '2'	System	03 Nov 2020 20:58:54

FDA-CBER-2022-1614-0005988

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (33)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '1'	System	03 Nov 2020 20:58:54

FDA-CBER-2022-1614-0005989

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (33)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '804 (804)'	System	03 Nov 2020 20:58:54

FDA-CBER-2022-1614-0005990

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 14:54:12

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:21:50
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: UMECLIDINIUM;VILANTEROL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 00:18:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 00:18:27
Data point term sent to Coder	System	03 Nov 2020 21:03:20
User entered 'Vilanterol/Umeclidinium'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 21:03:13

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (34)
Generated On: 09 Jun 2021 14:54:12
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:21:51
User entered 'No (N)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 21:03:13

FDA-CBER-2022-1614-0005992

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (34)
Generated On: 09 Jun 2021 14:54:12
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:22:20
User entered 'COPD- During hospitalization'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 21:03:13

FDA-CBER-2022-1614-0005993

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 14:54:12

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of number of puffs as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	08 Jan 2021 08:31:09
Query 'Per DM CLR: Please provide the actual dose for this medication instead of number of puffs as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'Dosage not known.' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	07 Dec 2020 17:21:10
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of number of puffs as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 18:18:07
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:22:22
User entered '1'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 21:03:13

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (34)
Generated On: 09 Jun 2021 14:54:12
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:22:24
User entered 'puff (PUFF)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 21:03:13

FDA-CBER-2022-1614-0005995

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (34)
Generated On: 09 Jun 2021 14:54:12
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:22:25
User entered empty.	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 21:03:13

FDA-CBER-2022-1614-0005996

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (34)
Generated On: 09 Jun 2021 14:54:12
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:22:27
User entered 'as needed (PRN)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 21:03:13

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (34)
Generated On: 09 Jun 2021 14:54:12
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:22:32
User entered empty.	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 21:03:13

FDA-CBER-2022-1614-0005998

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (34)
Generated On: 09 Jun 2021 14:54:12
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:22:33
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 21:03:13

FDA-CBER-2022-1614-0005999

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (34)
Generated On: 09 Jun 2021 14:54:12
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:22:35
User entered empty.	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 21:03:13

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (34)
Generated On: 09 Jun 2021 14:54:12
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:22:36
User entered '29 Sep 2020'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 21:03:13

FDA-CBER-2022-1614-0006001

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (34)
Generated On: 09 Jun 2021 14:54:12
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:22:38
User entered '0'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 21:03:13

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (34)
Generated On: 09 Jun 2021 14:54:12
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:22:39
User entered 'No (N)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 21:03:13

FDA-CBER-2022-1614-0006003

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (34)
Generated On: 09 Jun 2021 14:54:12
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:32:54
DataPoint Un-verified.	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 20:31:21
User entered '12 Oct 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 20:31:21
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:22:41
User entered '13 Oct 2020'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 21:03:13

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (34)
Generated On: 09 Jun 2021 14:54:12
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 20:22:44
User entered 'No (N)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 21:03:13

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (34)
Generated On: 09 Jun 2021 14:54:12
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	03 Nov 2020 21:03:13

FDA-CBER-2022-1614-0006006

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (34)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	03 Nov 2020 21:03:13

FDA-CBER-2022-1614-0006007

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (34)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	03 Nov 2020 21:03:13

FDA-CBER-2022-1614-0006008

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 14:54:12

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:33:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: VORTIOXETINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 00:16:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 00:16:29
Data point term sent to Coder	System	03 Nov 2020 21:04:21
User entered 'Vortioxetine'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 21:03:59

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (35)
Generated On: 09 Jun 2021 14:54:12
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:33:04
User entered 'No (N)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 21:03:59

FDA-CBER-2022-1614-0006010

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (35)
Generated On: 09 Jun 2021 14:54:12
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:33:05
User entered 'Depression - During hospitalization'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 21:03:59

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (35)
Generated On: 09 Jun 2021 14:54:12
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:33:07
User entered '20'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 21:03:59

FDA-CBER-2022-1614-0006012

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (35)
Generated On: 09 Jun 2021 14:54:12
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:33:08
User entered 'mg (mg)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 21:03:59

FDA-CBER-2022-1614-0006013

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (35)
Generated On: 09 Jun 2021 14:54:12
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:33:09
User entered empty.	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 21:03:59

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (35)
Generated On: 09 Jun 2021 14:54:12
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:33:11
User entered 'once daily (QD)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 21:03:59

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (35)
Generated On: 09 Jun 2021 14:54:12
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:33:12
User entered empty.	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 21:03:59

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (35)
Generated On: 09 Jun 2021 14:54:12
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:33:14
User entered 'Oral (ORAL)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 21:03:59

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (35)
Generated On: 09 Jun 2021 14:54:12
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:33:18
DataPoint Un-verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:33:17
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:33:15
User entered empty.	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 21:03:59

FDA-CBER-2022-1614-0006018

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (35)
Generated On: 09 Jun 2021 14:54:12
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:33:20
User entered '29 Sep 2020'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 21:03:59

FDA-CBER-2022-1614-0006019

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (35)
Generated On: 09 Jun 2021 14:54:12
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:33:21
User entered '0'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 21:03:59

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (35)
Generated On: 09 Jun 2021 14:54:12
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:33:23
User entered 'No (N)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 21:03:59

FDA-CBER-2022-1614-0006021

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (35)
Generated On: 09 Jun 2021 14:54:12
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:33:24
User entered '12 Oct 2020' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 20:31:31
User entered '13 Oct 2020'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 21:03:59

FDA-CBER-2022-1614-0006022

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (35)
Generated On: 09 Jun 2021 14:54:12
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:33:27
User entered 'No (N)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 21:03:59

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (35)
Generated On: 09 Jun 2021 14:54:12
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '1'	(b) (4), (b) (6) System	03 Nov 2020 21:03:59

FDA-CBER-2022-1614-0006024

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (35)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '1'	System	03 Nov 2020 21:03:59

FDA-CBER-2022-1614-0006025

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (35)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '804 (804)'	(b) (4), (b) (6) System	03 Nov 2020 21:03:59

FDA-CBER-2022-1614-0006026

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (36)
Generated On: 09 Jun 2021 14:54:12
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:46:58
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Un-verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 22:06:08
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 22:06:01
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 21:43:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 21:43:00
Data point term sent to Coder	System	24 Nov 2020 21:41:43
User entered 'Influenza Vaccine'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:41:24
DataPoint activated with code reason code Data required.	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:40:31
DataPoint inactivated with code reason code Data not required.	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 21:05:36

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (36)
Generated On: 09 Jun 2021 14:54:12
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:47:01
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Un-verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 22:06:06
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 22:06:03
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:41:24
DataPoint activated with code reason code Data required.	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:40:31
DataPoint inactivated with code reason code Data not required.	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 21:05:36

FDA-CBER-2022-1614-0006028

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (36)
Generated On: 09 Jun 2021 14:54:12
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:47:03
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Influenza Prevention'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:41:24
DataPoint activated with code reason code Data required.	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:40:31
DataPoint inactivated with code reason code Data not required.	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 21:05:36

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (36)
Generated On: 09 Jun 2021 14:54:12
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:47:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0.5'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:41:24
DataPoint activated with code reason code Data required.	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:40:31
DataPoint inactivated with code reason code Data not required.	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 21:05:36

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (36)
Generated On: 09 Jun 2021 14:54:12
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:47:12
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'mL (mL)'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:41:24
DataPoint activated with code reason code Data required.	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:40:31
DataPoint inactivated with code reason code Data not required.	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 21:05:36

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 14:54:12

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:47:14
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:41:24
DataPoint activated with code reason code Data required.	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:40:31
DataPoint inactivated with code reason code Data not required.	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 21:05:36

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (36)
Generated On: 09 Jun 2021 14:54:12
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:47:16
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'once (ONCE)'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:41:24
DataPoint activated with code reason code Data required.	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:40:31
DataPoint inactivated with code reason code Data not required.	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 21:05:36

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 14:54:12

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:47:17
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:41:24
DataPoint activated with code reason code Data required.	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:40:31
DataPoint inactivated with code reason code Data not required.	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 21:05:36

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (36)
Generated On: 09 Jun 2021 14:54:12
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:47:19
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Intramuscular (INTRAMUSCULAR)'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:41:24
DataPoint activated with code reason code Data required.	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:40:31
DataPoint inactivated with code reason code Data not required.	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 21:05:36

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 14:54:12

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:47:20
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:41:24
DataPoint activated with code reason code Data required.	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:40:31
DataPoint inactivated with code reason code Data not required.	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 21:05:36

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 14:54:12

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:47:22
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '23 Oct 2020'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:41:24
DataPoint activated with code reason code Data required.	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:40:31
DataPoint inactivated with code reason code Data not required.	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 21:05:36

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (36)
Generated On: 09 Jun 2021 14:54:12
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:47:23
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:41:24
DataPoint activated with code reason code Data required.	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:40:31
DataPoint inactivated with code reason code Data not required.	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 21:05:36

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US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (36)
Generated On: 09 Jun 2021 14:54:12
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:47:25
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:41:24
DataPoint activated with code reason code Data required.	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:40:31
DataPoint inactivated with code reason code Data not required.	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 21:05:36

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 14:54:12

If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:47:26
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '23 Oct 2020'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:41:24
DataPoint activated with code reason code Data required.	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:40:31
DataPoint inactivated with code reason code Data not required.	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 21:05:36

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 14:54:12

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:47:27
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:41:24
DataPoint activated with code reason code Data required.	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:40:31
DataPoint inactivated with code reason code Data not required.	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 21:05:36

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 14:54:12

Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	24 Nov 2020 21:41:24
DataPoint activated with code reason code Data required.	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:40:31
DataPoint inactivated with code reason code Data not required.	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 21:05:36

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 14:54:12

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	24 Nov 2020 21:41:24
DataPoint activated with code reason code Data required.	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:40:31
DataPoint inactivated with code reason code Data not required.	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 21:05:36

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 14:54:12

Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	24 Nov 2020 21:41:24
DataPoint activated with code reason code Data required.	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:40:31
DataPoint inactivated with code reason code Data not required.	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 21:05:36

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 14:54:12

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:47:32
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: VARICELLA ZOSTER VACCINES, PRODUCT: VARICELLA ZOSTER VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 21:49:04
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 21:49:04
Data point term sent to Coder	System	24 Nov 2020 21:47:51
User entered 'Shingles Vaccine'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:46:53

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (37)
Generated On: 09 Jun 2021 14:54:12
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:47:33
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:46:53

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US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (37)
Generated On: 09 Jun 2021 14:54:12
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:47:36
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Shingles Prevention'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:46:53

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 14:54:12

Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:47:38
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Feb 2021 10:32:07
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'Updated' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	28 Jan 2021 20:16:03
User entered '0.5' reason for change: Data Entry Error	Jennifer Leyva (b) (4) (b) (4)	28 Jan 2021 20:15:59
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	28 Jan 2021 09:10:03
User entered '05'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:46:53

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (37)
Generated On: 09 Jun 2021 14:54:12
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:47:39
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'mL (mL)'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:46:53

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (37)
Generated On: 09 Jun 2021 14:54:12
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:47:41
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:46:53

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US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (37)
Generated On: 09 Jun 2021 14:54:12
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:47:43
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'once (ONCE)'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:46:53

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (37)
Generated On: 09 Jun 2021 14:54:12
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:47:44
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:46:53

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (37)
Generated On: 09 Jun 2021 14:54:12
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:47:46
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Intramuscular (INTRAMUSCULAR)'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:46:53

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (37)
Generated On: 09 Jun 2021 14:54:12
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:47:47
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:46:53

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US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (37)
Generated On: 09 Jun 2021 14:54:12
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:47:49
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '27 Oct 2020'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:46:53

FDA-CBER-2022-1614-0006055

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (37)
Generated On: 09 Jun 2021 14:54:12
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:47:50
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:46:53

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (37)
Generated On: 09 Jun 2021 14:54:12
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:47:52
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:46:53

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (37)
Generated On: 09 Jun 2021 14:54:12
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:47:53
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '27 Oct 2020'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:46:53

FDA-CBER-2022-1614-0006058

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (37)
Generated On: 09 Jun 2021 14:54:12
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:47:56
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:46:53

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (37)
Generated On: 09 Jun 2021 14:54:12
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	24 Nov 2020 21:46:53

FDA-CBER-2022-1614-0006060

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (37)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	24 Nov 2020 21:46:53

FDA-CBER-2022-1614-0006061

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (37)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	24 Nov 2020 21:46:53

FDA-CBER-2022-1614-0006062

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 14:54:12

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:47:59
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS FOR URINARY FREQUENCY AND INCONTINENCE, PRODUCT: MIRABEGRON, PRODUCTSYNONYM: MYRBETRIQ - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 21:49:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 21:49:05
Data point term sent to Coder	System	24 Nov 2020 21:47:52
User entered 'Myrbetriq'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:47:16

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (38)
Generated On: 09 Jun 2021 14:54:12
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:48:01
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:47:16

FDA-CBER-2022-1614-0006064

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (38)
Generated On: 09 Jun 2021 14:54:12
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:48:03
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Overactive Bladder'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:47:16

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (38)
Generated On: 09 Jun 2021 14:54:12
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:48:05
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '25'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:47:16

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (38)
Generated On: 09 Jun 2021 14:54:12
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:48:07
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'mg (mg)'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:47:16

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (38)
Generated On: 09 Jun 2021 14:54:12
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:48:08
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:47:16

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US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (38)
Generated On: 09 Jun 2021 14:54:12
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:48:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'once daily (QD)'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:47:16

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (38)
Generated On: 09 Jun 2021 14:54:12
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:48:11
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:47:16

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (38)
Generated On: 09 Jun 2021 14:54:12
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:48:12
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Oral (ORAL)'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:47:16

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (38)
Generated On: 09 Jun 2021 14:54:12
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:48:14
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:47:16

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US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 14:54:12

Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:48:16
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User closed query 'Per DM CLR: Con Med MYRBETRIQ was added/changed on 03 NOV 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	08 Dec 2020 06:25:23
Query 'Per DM CLR: Con Med MYRBETRIQ was added/changed on 03 NOV 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' answered with 'Not worsening. Previously untreated at study entry.' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	07 Dec 2020 17:22:47
User opened query 'Per DM CLR: Con Med MYRBETRIQ was added/changed on 03 NOV 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 18:18:25
User entered '03 Nov 2020'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:47:16

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (38)
Generated On: 09 Jun 2021 14:54:12
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:48:18
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:47:16

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (38)
Generated On: 09 Jun 2021 14:54:12
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:48:21
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:47:16

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (38)
Generated On: 09 Jun 2021 14:54:12
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:48:20
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:47:16

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US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (38)
Generated On: 09 Jun 2021 14:54:12
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:48:23
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:47:16

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (38)
Generated On: 09 Jun 2021 14:54:12
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '1'	System	24 Nov 2020 21:47:16

FDA-CBER-2022-1614-0006078

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (38)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '1'	System	24 Nov 2020 21:47:16

FDA-CBER-2022-1614-0006079

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (38)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '804 (804)'	(b) (4), (b) (6) System	24 Nov 2020 21:47:16

FDA-CBER-2022-1614-0006080

US3012098

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 14:54:12

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: SYNTHETIC ANTICHOLINERGICS, ESTERS WITH TERTIARY AMINO GROUP, PRODUCT: DICYCLOVERINE, PRODUCTSYNONYM: DICYCLOMINE [DICYCLOVERINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 05:15:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 05:15:18
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 22:06:29
Data point term sent to Coder	System	24 Nov 2020 21:47:52
User entered 'Dicyclomine'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:47:45

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (39)
Generated On: 09 Jun 2021 14:54:12
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 22:06:31
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:47:45

FDA-CBER-2022-1614-0006082

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (39)
Generated On: 09 Jun 2021 14:54:12
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 22:06:32
User entered 'Colitis prevention'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:47:45

FDA-CBER-2022-1614-0006083

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (39)
Generated On: 09 Jun 2021 14:54:12
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 22:06:34
User entered '20'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:47:45

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (39)
Generated On: 09 Jun 2021 14:54:12
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 22:06:37
User entered 'mg (mg)'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:47:45

FDA-CBER-2022-1614-0006085

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (39)
Generated On: 09 Jun 2021 14:54:12
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 22:06:39
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:47:45

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (39)
Generated On: 09 Jun 2021 14:54:12
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 22:06:41
User entered 'as needed (PRN)'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:47:45

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (39)
Generated On: 09 Jun 2021 14:54:12
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 22:06:42
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:47:45

FDA-CBER-2022-1614-0006088

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (39)
Generated On: 09 Jun 2021 14:54:12
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 22:06:43
User entered 'Oral (ORAL)'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:47:45

FDA-CBER-2022-1614-0006089

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (39)
Generated On: 09 Jun 2021 14:54:12
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 22:06:45
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:47:45

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (39)
Generated On: 09 Jun 2021 14:54:12
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 22:06:48
User entered '13 Oct 2020'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:47:45

FDA-CBER-2022-1614-0006091

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (39)
Generated On: 09 Jun 2021 14:54:12
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 22:06:49
User entered '0'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:47:45

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (39)
Generated On: 09 Jun 2021 14:54:12
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 22:06:51
User entered 'Yes (Y)'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:47:45

FDA-CBER-2022-1614-0006093

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (39)
Generated On: 09 Jun 2021 14:54:12
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 22:06:53
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:47:45

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (39)
Generated On: 09 Jun 2021 14:54:12
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 22:06:54
User entered 'No (N)'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:47:45

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (39)
Generated On: 09 Jun 2021 14:54:12
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	24 Nov 2020 21:47:45

FDA-CBER-2022-1614-0006096

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (39)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	24 Nov 2020 21:47:45

FDA-CBER-2022-1614-0006097

US3012098
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (39)
Generated On: 09 Jun 2021 14:54:12
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered empty.	System	24 Nov 2020 21:47:45

FDA-CBER-2022-1614-0006098

US3012098
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Generated On: 09 Jun 2021 14:54:12
Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:53:03
User entered 'Yes (Y)' reason for change: New Information	Jennifer Leyva (b) (4) (b) (4)	28 Oct 2020 22:06:49
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:30:15
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	11 Aug 2020 01:29:54

US3012098
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (1)
Generated On: 09 Jun 2021 14:54:12
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:53:26
User entered '29 Sep 2020'	Jennifer Leyva (b) (4) (b) (4)	28 Oct 2020 22:09:49

US3012098
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (1)
Generated On: 09 Jun 2021 14:54:12
Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4), (b) (6) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:53:26
User entered 'Chest CT for pulmonary embolus, negative'	Jennifer Leyva (b) (4) (b) (4), (b) (6) (b) (4)	28 Oct 2020 22:09:49

US3012098
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (1)
Generated On: 09 Jun 2021 14:54:12
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:53:26
User entered 'Adverse Event (AE)'	Jennifer Leyva (b) (4) (b) (4)	28 Oct 2020 22:09:49

US3012098
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (1)
Generated On: 09 Jun 2021 14:54:12
If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:53:26
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	28 Oct 2020 22:09:49

US3012098
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (2)
Generated On: 09 Jun 2021 14:54:12
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:53:26
User entered '14 Oct 2020'	Jennifer Leyva (b) (4) (b) (4)	28 Oct 2020 22:10:18

FDA-CBER-2022-1614-0006104

US3012098
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (2)
Generated On: 09 Jun 2021 14:54:12
Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User closed query 'Per CDM re-query: As per the response, the diagnostic test performed while subject was hospitalized, however the date of discharge from hospital recorded on AE is two days prior (12Oct2020) to the Concomitant procedure. Please review and confirm if the dates are correct. Update accordingly. Otherwise clarify. Thank you.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	18 Dec 2020 05:46:25
Query 'Per CDM re-query: As per the response, the diagnostic test performed while subject was hospitalized, however the date of discharge from hospital recorded on AE is two days prior (12Oct2020) to the Concomitant procedure. Please review and confirm if the dates are correct. Update accordingly. Otherwise clarify. Thank you.' answered with 'corrected' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	17 Dec 2020 14:02:12
User opened query 'Per CDM re-query: As per the response, the diagnostic test performed while subject was hospitalized, however the date of discharge from hospital recorded on AE is two days prior (12Oct2020) to the Concomitant procedure. Please review and confirm if the dates are correct. Update accordingly. Otherwise clarify. Thank you.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	17 Dec 2020 13:34:27
User closed query 'Per CDM: As per CCG SARS-CoV2 diagnostic test has to be recorded under Covid-19 assessment folder. Please review reconcile and update accordingly. Otherwise clarify. Thank you.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	17 Dec 2020 05:24:49
Query 'Per CDM: As per CCG SARS-CoV2 diagnostic test has to be recorded under Covid-19 assessment folder. Please review reconcile and update accordingly. Otherwise clarify. Thank you.' answered with 'Test not performed in clinic, done while hospitalized per standard procedures' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	08 Dec 2020 20:31:00

FDA-CBER-2022-1614-0006105

US3012098

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:54:12

Procedure/Surgery

Audit	User	Time (GMT)
User opened query 'Per CDM: As per CCG SARS-CoV2 diagnostic test has to be recorded under Covid-19 assessment folder. Please review reconcile and update accordingly. Otherwise clarify. Thank you.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	07 Dec 2020 17:55:41
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:53:26
User entered 'SARS-CoV-2 test (nasal, negative)'	Jennifer Leyva (b) (4) (b) (4)	28 Oct 2020 22:10:18

US3012098
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (2)
Generated On: 09 Jun 2021 14:54:12
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:53:26
User entered 'Adverse Event (AE)'	Jennifer Leyva (b) (4) (b) (4)	28 Oct 2020 22:10:18

FDA-CBER-2022-1614-0006107

US3012098
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (2)
Generated On: 09 Jun 2021 14:54:12
If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:53:26
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	28 Oct 2020 22:10:18

FDA-CBER-2022-1614-0006108

US3012098
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (3)
Generated On: 09 Jun 2021 14:54:12
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:34:32
User entered '29 Sep 2020'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 21:04:45

FDA-CBER-2022-1614-0006109

US3012098
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (3)
Generated On: 09 Jun 2021 14:54:12
Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:34:33
User entered 'GI Panel- Bacteria PCR - Negative'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 21:04:45

US3012098
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (3)
Generated On: 09 Jun 2021 14:54:12
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:34:35
User entered 'Diagnostic (DIAGNOSTIC)'	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 21:04:45

FDA-CBER-2022-1614-0006111

US3012098
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (3)
Generated On: 09 Jun 2021 14:54:12
If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 21:34:36
User entered empty.	Pamela Fidler (b) (4) (b) (4) (b) (4)	03 Nov 2020 21:04:45

FDA-CBER-2022-1614-0006112

US3012098
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (4)
Generated On: 09 Jun 2021 14:54:12
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 22:05:34
User entered '30 Sep 2020'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:37:58

FDA-CBER-2022-1614-0006113

US3012098
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (4)
Generated On: 09 Jun 2021 14:54:12
Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4), (b) (6) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 22:05:34
User entered 'CHEST CT FOR PULMONARY EMBOLUS, NEGATIVE'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:37:58

FDA-CBER-2022-1614-0006114

US3012098
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (4)
Generated On: 09 Jun 2021 14:54:12
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User closed query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 02:39:29
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
Query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. ' answered with 'AE updated' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	03 Mar 2021 18:14:44
User opened query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 13:37:27
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 22:05:34
User entered 'Adverse Event (AE)'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:37:58

FDA-CBER-2022-1614-0006115

US3012098
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (4)
Generated On: 09 Jun 2021 14:54:12
If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 22:05:34
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:37:58

FDA-CBER-2022-1614-0006116

US3012098
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (5)
Generated On: 09 Jun 2021 14:54:12
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 22:05:34
User entered '29 Sep 2020'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:39:25

FDA-CBER-2022-1614-0006117

US3012098
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (5)
Generated On: 09 Jun 2021 14:54:12
Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4), (b) (6) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 22:05:34
User entered 'CT Scan - Abdomen/Pelvis for diagnosis, Normal'	Jennifer Leyva (b) (4) (b) (4), (b) (6) (b) (4)	24 Nov 2020 21:39:25

FDA-CBER-2022-1614-0006118

US3012098
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (5)
Generated On: 09 Jun 2021 14:54:12
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User closed query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 02:39:39
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
Query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. ' answered with 'AE updated' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	03 Mar 2021 18:14:48
User opened query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 13:38:16
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 22:05:34
User entered 'Adverse Event (AE)'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:39:25

US3012098
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (5)
Generated On: 09 Jun 2021 14:54:12
If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 22:05:34
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:39:25

US3012098
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (6)
Generated On: 09 Jun 2021 14:54:12
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 22:05:34
User entered '30 Sep 2020'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:39:46

FDA-CBER-2022-1614-0006121

US3012098
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (6)
Generated On: 09 Jun 2021 14:54:12
Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 22:05:34
User entered 'Transthoracic Echocardiograph'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:39:46

US3012098
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (6)
Generated On: 09 Jun 2021 14:54:12
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User closed query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 02:39:49
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
Query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. ' answered with 'AE updated' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	03 Mar 2021 18:14:52
User opened query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 13:40:59
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 22:05:34
User entered 'Adverse Event (AE)'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:39:46

US3012098
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (6)
Generated On: 09 Jun 2021 14:54:12
If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 22:05:34
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:39:46

US3012098
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (7)
Generated On: 09 Jun 2021 14:54:12
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 22:05:34
User entered '29 Sep 2020'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:40:02

FDA-CBER-2022-1614-0006125

US3012098
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (7)
Generated On: 09 Jun 2021 14:54:12
Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 22:05:34
User entered 'Electrocardiogram'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:40:02

FDA-CBER-2022-1614-0006126

US3012098
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (7)
Generated On: 09 Jun 2021 14:54:12
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User closed query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 02:40:03
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
Query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. ' answered with 'AE updated' (Site from DM).	Jennifer Leyva (b) (4) (b) (4)	03 Mar 2021 18:15:06
User opened query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 13:41:22
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 22:05:34
User entered 'Adverse Event (AE)'	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:40:02

FDA-CBER-2022-1614-0006127

US3012098
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (7)
Generated On: 09 Jun 2021 14:54:12
If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 22:05:34
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	24 Nov 2020 21:40:02

FDA-CBER-2022-1614-0006128

US3012098
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 14:54:12
Date of study discontinuation/completion *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:13:01
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '02 Dec 2020'	Jennifer Leyva (b) (4) (b) (4)	02 Dec 2020 16:07:28

FDA-CBER-2022-1614-0006129

US3012098
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 14:54:12
Reason for discontinuation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:13:01
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Withdrawal of consent by participant (specify) (WITHDRAWAL OF CONSENT)'	Jennifer Leyva (b) (4) (b) (4)	02 Dec 2020 16:07:28

US3012098

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:54:12

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) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:13:01
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered 'Subject withdrew for personal reasons'	Jennifer Leyva (b) (4) (b) (4)	02 Dec 2020 16:07:28

US3012098
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 14:54:12
If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:13:01
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Dec 2020 16:07:28

US3012098
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 14:54:12
If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:13:01
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Dec 2020 16:07:28

FDA-CBER-2022-1614-0006133

US3012098
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 14:54:12
Date of death *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:13:01
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Dec 2020 16:07:28

FDA-CBER-2022-1614-0006134

US3012098
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 09 Jun 2021 14:54:12
Was autopsy performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:13:01
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered empty.	Jennifer Leyva (b) (4) (b) (4)	02 Dec 2020 16:07:28

FDA-CBER-2022-1614-0006135

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
Un-reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:47
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:43
User entered 'USA-US006-2020-MRNA-1273-P301000002'	System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006136

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Yes (Y)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Yes (Y)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Laurence'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Chu'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered '3100 Red River Street'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006146

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Austin'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'TX'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006148

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered '78705'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006149

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	12 Oct 2020 15:58:11
User entered 'US'	(b) (4), (b) (6) System	02 Oct 2020 12:35:56

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '18'	System	09 Mar 2021 14:58:51
User entered '17'	System	04 Mar 2021 13:33:28
User entered '16'	System	14 Jan 2021 16:31:53
User entered '15'	System	10 Dec 2020 19:04:59
User entered '14'	System	08 Dec 2020 14:58:45
User entered '13'	System	05 Dec 2020 17:59:24
User entered '12'	System	25 Nov 2020 18:59:34
User entered '11'	System	19 Nov 2020 17:47:54
User entered '10'	System	19 Nov 2020 16:31:32
User entered '9'	System	11 Nov 2020 16:58:44
User entered '8'	System	06 Nov 2020 17:51:29
User entered '7'	System	04 Nov 2020 14:12:15
User entered '6'	System	02 Nov 2020 15:22:19
User entered '5'	System	30 Oct 2020 13:58:29
User entered '4'	System	21 Oct 2020 16:35:42
User entered '3'	System	14 Oct 2020 13:51:59
User entered '2'	System	12 Oct 2020 15:58:20
User entered '1'	System	02 Oct 2020 12:35:56

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4), (b) (6) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
Un-reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:47
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:43
User entered 'USA-US006-2020-MRNA-1273-P301000002'	System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Yes (Y)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006153

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Yes (Y)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006156

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006158

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006159

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Laurence'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Chu'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered '3100 Red River Street'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006162

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Austin'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006163

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'TX'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006164

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered '78705'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006165

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	12 Oct 2020 15:58:11
User entered 'US'	(b) (4), (b) (6) System	02 Oct 2020 12:35:56

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '18'	System	09 Mar 2021 14:58:51
User entered '17'	System	04 Mar 2021 13:33:28
User entered '16'	System	14 Jan 2021 16:31:53
User entered '15'	System	10 Dec 2020 19:04:59
User entered '14'	System	08 Dec 2020 14:58:45
User entered '13'	System	05 Dec 2020 17:59:24
User entered '12'	System	25 Nov 2020 18:59:34
User entered '11'	System	19 Nov 2020 17:47:54
User entered '10'	System	19 Nov 2020 16:31:32
User entered '9'	System	11 Nov 2020 16:58:44
User entered '8'	System	06 Nov 2020 17:51:29
User entered '7'	System	04 Nov 2020 14:12:15
User entered '6'	System	02 Nov 2020 15:22:19
User entered '5'	System	30 Oct 2020 13:58:29
User entered '4'	System	21 Oct 2020 16:35:42
User entered '3'	System	14 Oct 2020 13:51:59
User entered '2'	System	12 Oct 2020 15:58:20
User entered '1'	System	02 Oct 2020 12:35:56

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form (1)
Generated On: 09 Jun 2021 14:54:12
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
User entered '02/Oct/2020 12:35'	System	02 Oct 2020 12:35:56

FDA-CBER-2022-1614-0006168

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:54:12

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) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4), (b) (6)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	12 Oct 2020 15:58:11
User entered '1'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:56

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4), (b) (6) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
Un-reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:47
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:43
User entered 'USA-US006-2020-MRNA-1273-P301000002'	System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Yes (Y)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006172

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Yes (Y)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006174

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006175

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006176

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Laurence'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Chu'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006179

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered '3100 Red River Street'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006180

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Austin'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'TX'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered '78705'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	12 Oct 2020 15:58:11
User entered 'US'	(b) (4), (b) (6) System	02 Oct 2020 12:35:56

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '18'	System	09 Mar 2021 14:58:51
User entered '17'	System	04 Mar 2021 13:33:28
User entered '16'	System	14 Jan 2021 16:31:53
User entered '15'	System	10 Dec 2020 19:04:59
User entered '14'	System	08 Dec 2020 14:58:45
User entered '13'	System	05 Dec 2020 17:59:24
User entered '12'	System	25 Nov 2020 18:59:34
User entered '11'	System	19 Nov 2020 17:47:54
User entered '10'	System	19 Nov 2020 16:31:32
User entered '9'	System	11 Nov 2020 16:58:44
User entered '8'	System	06 Nov 2020 17:51:29
User entered '7'	System	04 Nov 2020 14:12:15
User entered '6'	System	02 Nov 2020 15:22:19
User entered '5'	System	30 Oct 2020 13:58:29
User entered '4'	System	21 Oct 2020 16:35:42
User entered '3'	System	14 Oct 2020 13:51:59
User entered '2'	System	12 Oct 2020 15:58:20
User entered '1'	System	02 Oct 2020 12:35:56

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form (2)
Generated On: 09 Jun 2021 14:54:12
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
User entered '12/Oct/2020 15:58'	System	12 Oct 2020 15:58:20

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:54:12

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) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	14 Oct 2020 13:51:48
User entered '1'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	12 Oct 2020 15:58:20

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
Un-reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:47
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:43
User entered 'USA-US006-2020-MRNA-1273-P301000002'	System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006188

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Yes (Y)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006189

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Yes (Y)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006192

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Laurence'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Chu'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered '3100 Red River Street'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006198

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Austin'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006199

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'TX'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006200

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered '78705'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	12 Oct 2020 15:58:11
User entered 'US'	(b) (4), (b) (6) System	02 Oct 2020 12:35:56

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '18'	System	09 Mar 2021 14:58:51
User entered '17'	System	04 Mar 2021 13:33:28
User entered '16'	System	14 Jan 2021 16:31:53
User entered '15'	System	10 Dec 2020 19:04:59
User entered '14'	System	08 Dec 2020 14:58:45
User entered '13'	System	05 Dec 2020 17:59:24
User entered '12'	System	25 Nov 2020 18:59:34
User entered '11'	System	19 Nov 2020 17:47:54
User entered '10'	System	19 Nov 2020 16:31:32
User entered '9'	System	11 Nov 2020 16:58:44
User entered '8'	System	06 Nov 2020 17:51:29
User entered '7'	System	04 Nov 2020 14:12:15
User entered '6'	System	02 Nov 2020 15:22:19
User entered '5'	System	30 Oct 2020 13:58:29
User entered '4'	System	21 Oct 2020 16:35:42
User entered '3'	System	14 Oct 2020 13:51:59
User entered '2'	System	12 Oct 2020 15:58:20
User entered '1'	System	02 Oct 2020 12:35:56

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form (3)
Generated On: 09 Jun 2021 14:54:12
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
User entered '14/Oct/2020 13:51'	System	14 Oct 2020 13:51:59

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:54:12

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) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	30 Oct 2020 13:58:21
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
User entered '1'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	14 Oct 2020 13:51:59

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4), (b) (6) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
Un-reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:47
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:43
User entered 'USA-US006-2020-MRNA-1273-P301000002'	System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Yes (Y)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006209

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Yes (Y)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006210

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006211

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Laurence'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Chu'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered '3100 Red River Street'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006216

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Austin'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006217

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'TX'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered '78705'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006219

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	12 Oct 2020 15:58:11
User entered 'US'	(b) (4), (b) (6) System	02 Oct 2020 12:35:56

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '18'	System	09 Mar 2021 14:58:51
User entered '17'	System	04 Mar 2021 13:33:28
User entered '16'	System	14 Jan 2021 16:31:53
User entered '15'	System	10 Dec 2020 19:04:59
User entered '14'	System	08 Dec 2020 14:58:45
User entered '13'	System	05 Dec 2020 17:59:24
User entered '12'	System	25 Nov 2020 18:59:34
User entered '11'	System	19 Nov 2020 17:47:54
User entered '10'	System	19 Nov 2020 16:31:32
User entered '9'	System	11 Nov 2020 16:58:44
User entered '8'	System	06 Nov 2020 17:51:29
User entered '7'	System	04 Nov 2020 14:12:15
User entered '6'	System	02 Nov 2020 15:22:19
User entered '5'	System	30 Oct 2020 13:58:29
User entered '4'	System	21 Oct 2020 16:35:42
User entered '3'	System	14 Oct 2020 13:51:59
User entered '2'	System	12 Oct 2020 15:58:20
User entered '1'	System	02 Oct 2020 12:35:56

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form (4)
Generated On: 09 Jun 2021 14:54:12
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
User entered '21/Oct/2020 12:35'	System	21 Oct 2020 16:35:42

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 14:54:12

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) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	30 Oct 2020 13:58:21
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
User entered '1'	(b) (4), (b) (6) (b) (4), (b) (6)	21 Oct 2020 16:35:42

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
Un-reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:47
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:43
User entered 'USA-US006-2020-MRNA-1273-P301000002'	System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006224

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Yes (Y)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Yes (Y)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006229

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Laurence'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Chu'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered '3100 Red River Street'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006234

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Austin'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006235

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'TX'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered '78705'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006237

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	12 Oct 2020 15:58:11
User entered 'US'	(b) (4), (b) (6) System	02 Oct 2020 12:35:56

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '18'	System	09 Mar 2021 14:58:51
User entered '17'	System	04 Mar 2021 13:33:28
User entered '16'	System	14 Jan 2021 16:31:53
User entered '15'	System	10 Dec 2020 19:04:59
User entered '14'	System	08 Dec 2020 14:58:45
User entered '13'	System	05 Dec 2020 17:59:24
User entered '12'	System	25 Nov 2020 18:59:34
User entered '11'	System	19 Nov 2020 17:47:54
User entered '10'	System	19 Nov 2020 16:31:32
User entered '9'	System	11 Nov 2020 16:58:44
User entered '8'	System	06 Nov 2020 17:51:29
User entered '7'	System	04 Nov 2020 14:12:15
User entered '6'	System	02 Nov 2020 15:22:19
User entered '5'	System	30 Oct 2020 13:58:29
User entered '4'	System	21 Oct 2020 16:35:42
User entered '3'	System	14 Oct 2020 13:51:59
User entered '2'	System	12 Oct 2020 15:58:20
User entered '1'	System	02 Oct 2020 12:35:56

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form (5)
Generated On: 09 Jun 2021 14:54:12
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	30 Oct 2020 15:50:56
User entered '30/Oct/2020 09:58'	System	30 Oct 2020 13:58:29

FDA-CBER-2022-1614-0006240

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 14:54:12

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) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Nov 2020 15:22:06
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	30 Oct 2020 15:50:58
User entered '1'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	30 Oct 2020 13:58:29

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
Un-reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:47
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:43
User entered 'USA-US006-2020-MRNA-1273-P301000002'	System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Yes (Y)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006244

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Yes (Y)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006249

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Laurence'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Chu'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered '3100 Red River Street'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006252

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Austin'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006253

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'TX'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered '78705'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006255

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	12 Oct 2020 15:58:11
User entered 'US'	(b) (4), (b) (6) System	02 Oct 2020 12:35:56

FDA-CBER-2022-1614-0006256

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '18'	System	09 Mar 2021 14:58:51
User entered '17'	System	04 Mar 2021 13:33:28
User entered '16'	System	14 Jan 2021 16:31:53
User entered '15'	System	10 Dec 2020 19:04:59
User entered '14'	System	08 Dec 2020 14:58:45
User entered '13'	System	05 Dec 2020 17:59:24
User entered '12'	System	25 Nov 2020 18:59:34
User entered '11'	System	19 Nov 2020 17:47:54
User entered '10'	System	19 Nov 2020 16:31:32
User entered '9'	System	11 Nov 2020 16:58:44
User entered '8'	System	06 Nov 2020 17:51:29
User entered '7'	System	04 Nov 2020 14:12:15
User entered '6'	System	02 Nov 2020 15:22:19
User entered '5'	System	30 Oct 2020 13:58:29
User entered '4'	System	21 Oct 2020 16:35:42
User entered '3'	System	14 Oct 2020 13:51:59
User entered '2'	System	12 Oct 2020 15:58:20
User entered '1'	System	02 Oct 2020 12:35:56

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form (6)
Generated On: 09 Jun 2021 14:54:12
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:53:20
User entered '02/Nov/2020 15:22'	System	02 Nov 2020 15:22:19

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 14:54:12

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) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:53:22
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	04 Nov 2020 14:12:07
User entered '1'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Nov 2020 15:22:19

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4), (b) (6) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
Un-reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:47
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:43
User entered 'USA-US006-2020-MRNA-1273-P301000002'	System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006260

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Yes (Y)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006261

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Yes (Y)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006264

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006265

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006266

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Laurence'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Chu'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006269

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered '3100 Red River Street'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Austin'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'TX'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered '78705'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	12 Oct 2020 15:58:11
User entered 'US'	(b) (4), (b) (6) System	02 Oct 2020 12:35:56

FDA-CBER-2022-1614-0006274

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '18'	System	09 Mar 2021 14:58:51
User entered '17'	System	04 Mar 2021 13:33:28
User entered '16'	System	14 Jan 2021 16:31:53
User entered '15'	System	10 Dec 2020 19:04:59
User entered '14'	System	08 Dec 2020 14:58:45
User entered '13'	System	05 Dec 2020 17:59:24
User entered '12'	System	25 Nov 2020 18:59:34
User entered '11'	System	19 Nov 2020 17:47:54
User entered '10'	System	19 Nov 2020 16:31:32
User entered '9'	System	11 Nov 2020 16:58:44
User entered '8'	System	06 Nov 2020 17:51:29
User entered '7'	System	04 Nov 2020 14:12:15
User entered '6'	System	02 Nov 2020 15:22:19
User entered '5'	System	30 Oct 2020 13:58:29
User entered '4'	System	21 Oct 2020 16:35:42
User entered '3'	System	14 Oct 2020 13:51:59
User entered '2'	System	12 Oct 2020 15:58:20
User entered '1'	System	02 Oct 2020 12:35:56

FDA-CBER-2022-1614-0006275

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form (7)
Generated On: 09 Jun 2021 14:54:12
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4), (b) (6)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:52:59
User entered '04/Nov/2020 09:12'	System	04 Nov 2020 14:12:15

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 14:54:12

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) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 16:58:34
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:53:01
User entered '1'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	04 Nov 2020 14:12:15

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4), (b) (6) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
Un-reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:47
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:43
User entered 'USA-US006-2020-MRNA-1273-P301000002'	System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006278

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Yes (Y)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Yes (Y)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006283

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006285

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Laurence'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Chu'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered '3100 Red River Street'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006288

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Austin'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006289

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'TX'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006290

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered '78705'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006291

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	12 Oct 2020 15:58:11
User entered 'US'	(b) (4), (b) (6) System	02 Oct 2020 12:35:56

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '18'	System	09 Mar 2021 14:58:51
User entered '17'	System	04 Mar 2021 13:33:28
User entered '16'	System	14 Jan 2021 16:31:53
User entered '15'	System	10 Dec 2020 19:04:59
User entered '14'	System	08 Dec 2020 14:58:45
User entered '13'	System	05 Dec 2020 17:59:24
User entered '12'	System	25 Nov 2020 18:59:34
User entered '11'	System	19 Nov 2020 17:47:54
User entered '10'	System	19 Nov 2020 16:31:32
User entered '9'	System	11 Nov 2020 16:58:44
User entered '8'	System	06 Nov 2020 17:51:29
User entered '7'	System	04 Nov 2020 14:12:15
User entered '6'	System	02 Nov 2020 15:22:19
User entered '5'	System	30 Oct 2020 13:58:29
User entered '4'	System	21 Oct 2020 16:35:42
User entered '3'	System	14 Oct 2020 13:51:59
User entered '2'	System	12 Oct 2020 15:58:20
User entered '1'	System	02 Oct 2020 12:35:56

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form (8)
Generated On: 09 Jun 2021 14:54:12
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:53:06
User entered '06/Nov/2020 12:51'	System	06 Nov 2020 17:51:29

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 14:54:12

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) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 16:58:34
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 14:53:08
User entered '1'	(b) (4), (b) (6) (b) (4), (b) (6)	06 Nov 2020 17:51:29

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4), (b) (6) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
Un-reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:47
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:43
User entered 'USA-US006-2020-MRNA-1273-P301000002'	System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006296

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Yes (Y)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006297

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006298

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006299

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Yes (Y)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006300

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Laurence'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Chu'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered '3100 Red River Street'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Austin'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'TX'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered '78705'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006309

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	12 Oct 2020 15:58:11
User entered 'US'	(b) (4), (b) (6) System	02 Oct 2020 12:35:56

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '18'	System	09 Mar 2021 14:58:51
User entered '17'	System	04 Mar 2021 13:33:28
User entered '16'	System	14 Jan 2021 16:31:53
User entered '15'	System	10 Dec 2020 19:04:59
User entered '14'	System	08 Dec 2020 14:58:45
User entered '13'	System	05 Dec 2020 17:59:24
User entered '12'	System	25 Nov 2020 18:59:34
User entered '11'	System	19 Nov 2020 17:47:54
User entered '10'	System	19 Nov 2020 16:31:32
User entered '9'	System	11 Nov 2020 16:58:44
User entered '8'	System	06 Nov 2020 17:51:29
User entered '7'	System	04 Nov 2020 14:12:15
User entered '6'	System	02 Nov 2020 15:22:19
User entered '5'	System	30 Oct 2020 13:58:29
User entered '4'	System	21 Oct 2020 16:35:42
User entered '3'	System	14 Oct 2020 13:51:59
User entered '2'	System	12 Oct 2020 15:58:20
User entered '1'	System	02 Oct 2020 12:35:56

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form (9)
Generated On: 09 Jun 2021 14:54:12
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	18 Nov 2020 15:48:36
User entered '11/Nov/2020 16:58'	System	11 Nov 2020 16:58:44

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 14:54:12

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) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 16:31:15
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	18 Nov 2020 15:48:36
User entered '1'	(b) (4), (b) (6)	11 Nov 2020 16:58:44

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
Un-reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:47
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:43
User entered 'USA-US006-2020-MRNA-1273-P301000002'	System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006314

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Yes (Y)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006315

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Yes (Y)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006318

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006319

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006321

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Laurence'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Chu'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered '3100 Red River Street'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006324

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Austin'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006325

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'TX'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006326

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered '78705'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006327

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	12 Oct 2020 15:58:11
User entered 'US'	(b) (4), (b) (6) System	02 Oct 2020 12:35:56

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '18'	System	09 Mar 2021 14:58:51
User entered '17'	System	04 Mar 2021 13:33:28
User entered '16'	System	14 Jan 2021 16:31:53
User entered '15'	System	10 Dec 2020 19:04:59
User entered '14'	System	08 Dec 2020 14:58:45
User entered '13'	System	05 Dec 2020 17:59:24
User entered '12'	System	25 Nov 2020 18:59:34
User entered '11'	System	19 Nov 2020 17:47:54
User entered '10'	System	19 Nov 2020 16:31:32
User entered '9'	System	11 Nov 2020 16:58:44
User entered '8'	System	06 Nov 2020 17:51:29
User entered '7'	System	04 Nov 2020 14:12:15
User entered '6'	System	02 Nov 2020 15:22:19
User entered '5'	System	30 Oct 2020 13:58:29
User entered '4'	System	21 Oct 2020 16:35:42
User entered '3'	System	14 Oct 2020 13:51:59
User entered '2'	System	12 Oct 2020 15:58:20
User entered '1'	System	02 Oct 2020 12:35:56

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form (10)
Generated On: 09 Jun 2021 14:54:12
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4), (b) (6) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	20 Nov 2020 16:40:31
User entered '19/Nov/2020 11:31'	System	19 Nov 2020 16:31:32

FDA-CBER-2022-1614-0006330

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form (10)

Generated On: 09 Jun 2021 14:54:12

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) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:59:22
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	20 Nov 2020 16:40:31
User entered '1'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 16:31:32

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
Un-reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:47
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:43
User entered 'USA-US006-2020-MRNA-1273-P301000002'	System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006332

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Yes (Y)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006333

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006334

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006335

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Yes (Y)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006337

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006339

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Laurence'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Chu'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered '3100 Red River Street'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Austin'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'TX'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered '78705'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006345

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	12 Oct 2020 15:58:11
User entered 'US'	(b) (4), (b) (6) System	02 Oct 2020 12:35:56

FDA-CBER-2022-1614-0006346

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '18'	System	09 Mar 2021 14:58:51
User entered '17'	System	04 Mar 2021 13:33:28
User entered '16'	System	14 Jan 2021 16:31:53
User entered '15'	System	10 Dec 2020 19:04:59
User entered '14'	System	08 Dec 2020 14:58:45
User entered '13'	System	05 Dec 2020 17:59:24
User entered '12'	System	25 Nov 2020 18:59:34
User entered '11'	System	19 Nov 2020 17:47:54
User entered '10'	System	19 Nov 2020 16:31:32
User entered '9'	System	11 Nov 2020 16:58:44
User entered '8'	System	06 Nov 2020 17:51:29
User entered '7'	System	04 Nov 2020 14:12:15
User entered '6'	System	02 Nov 2020 15:22:19
User entered '5'	System	30 Oct 2020 13:58:29
User entered '4'	System	21 Oct 2020 16:35:42
User entered '3'	System	14 Oct 2020 13:51:59
User entered '2'	System	12 Oct 2020 15:58:20
User entered '1'	System	02 Oct 2020 12:35:56

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form (11)
Generated On: 09 Jun 2021 14:54:12
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	20 Nov 2020 16:40:31
User entered '19/Nov/2020 12:47'	System	19 Nov 2020 17:47:54

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form (11)

Generated On: 09 Jun 2021 14:54:12

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) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 18:59:22
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	20 Nov 2020 16:40:31
User entered '1'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 17:47:54

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
Un-reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:47
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:43
User entered 'USA-US006-2020-MRNA-1273-P301000002'	System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006350

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Yes (Y)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006352

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006353

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Yes (Y)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006354

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006355

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006357

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Laurence'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006358

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Chu'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006359

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered '3100 Red River Street'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006360

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Austin'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'TX'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006362

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered '78705'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	12 Oct 2020 15:58:11
User entered 'US'	(b) (4), (b) (6) System	02 Oct 2020 12:35:56

FDA-CBER-2022-1614-0006364

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '18'	System	09 Mar 2021 14:58:51
User entered '17'	System	04 Mar 2021 13:33:28
User entered '16'	System	14 Jan 2021 16:31:53
User entered '15'	System	10 Dec 2020 19:04:59
User entered '14'	System	08 Dec 2020 14:58:45
User entered '13'	System	05 Dec 2020 17:59:24
User entered '12'	System	25 Nov 2020 18:59:34
User entered '11'	System	19 Nov 2020 17:47:54
User entered '10'	System	19 Nov 2020 16:31:32
User entered '9'	System	11 Nov 2020 16:58:44
User entered '8'	System	06 Nov 2020 17:51:29
User entered '7'	System	04 Nov 2020 14:12:15
User entered '6'	System	02 Nov 2020 15:22:19
User entered '5'	System	30 Oct 2020 13:58:29
User entered '4'	System	21 Oct 2020 16:35:42
User entered '3'	System	14 Oct 2020 13:51:59
User entered '2'	System	12 Oct 2020 15:58:20
User entered '1'	System	02 Oct 2020 12:35:56

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form (12)
Generated On: 09 Jun 2021 14:54:12
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	09 Dec 2020 15:42:07
User entered '25/Nov/2020 18:59'	System	25 Nov 2020 18:59:34

FDA-CBER-2022-1614-0006366

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form (12)

Generated On: 09 Jun 2021 14:54:12

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) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	09 Dec 2020 15:42:07
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	08 Dec 2020 14:58:34
User entered '1'	(b) (4), (b) (6)	25 Nov 2020 18:59:34

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4), (b) (6) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
Un-reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:47
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:43
User entered 'USA-US006-2020-MRNA-1273-P301000002'	System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Yes (Y)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006370

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Yes (Y)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006372

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006373

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006374

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006375

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Laurence'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Chu'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006377

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered '3100 Red River Street'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006378

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Austin'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006379

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'TX'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006380

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered '78705'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	12 Oct 2020 15:58:11
User entered 'US'	(b) (4), (b) (6) System	02 Oct 2020 12:35:56

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '18'	System	09 Mar 2021 14:58:51
User entered '17'	System	04 Mar 2021 13:33:28
User entered '16'	System	14 Jan 2021 16:31:53
User entered '15'	System	10 Dec 2020 19:04:59
User entered '14'	System	08 Dec 2020 14:58:45
User entered '13'	System	05 Dec 2020 17:59:24
User entered '12'	System	25 Nov 2020 18:59:34
User entered '11'	System	19 Nov 2020 17:47:54
User entered '10'	System	19 Nov 2020 16:31:32
User entered '9'	System	11 Nov 2020 16:58:44
User entered '8'	System	06 Nov 2020 17:51:29
User entered '7'	System	04 Nov 2020 14:12:15
User entered '6'	System	02 Nov 2020 15:22:19
User entered '5'	System	30 Oct 2020 13:58:29
User entered '4'	System	21 Oct 2020 16:35:42
User entered '3'	System	14 Oct 2020 13:51:59
User entered '2'	System	12 Oct 2020 15:58:20
User entered '1'	System	02 Oct 2020 12:35:56

FDA-CBER-2022-1614-0006383

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form (13)
Generated On: 09 Jun 2021 14:54:12
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	09 Dec 2020 15:42:07
User entered '05/Dec/2020 09:59'	System	05 Dec 2020 17:59:24

FDA-CBER-2022-1614-0006384

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form (13)

Generated On: 09 Jun 2021 14:54:12

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) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	09 Dec 2020 15:42:07
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	08 Dec 2020 14:58:34
User entered '1'	(b) (4), (b) (6)	05 Dec 2020 17:59:24

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
Un-reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:47
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:43
User entered 'USA-US006-2020-MRNA-1273-P301000002'	System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006386

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Yes (Y)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006388

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006389

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Yes (Y)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006391

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006393

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Laurence'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Chu'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006395

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered '3100 Red River Street'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006396

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Austin'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006397

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'TX'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006398

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered '78705'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006399

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	12 Oct 2020 15:58:11
User entered 'US'	(b) (4), (b) (6) System	02 Oct 2020 12:35:56

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '18'	System	09 Mar 2021 14:58:51
User entered '17'	System	04 Mar 2021 13:33:28
User entered '16'	System	14 Jan 2021 16:31:53
User entered '15'	System	10 Dec 2020 19:04:59
User entered '14'	System	08 Dec 2020 14:58:45
User entered '13'	System	05 Dec 2020 17:59:24
User entered '12'	System	25 Nov 2020 18:59:34
User entered '11'	System	19 Nov 2020 17:47:54
User entered '10'	System	19 Nov 2020 16:31:32
User entered '9'	System	11 Nov 2020 16:58:44
User entered '8'	System	06 Nov 2020 17:51:29
User entered '7'	System	04 Nov 2020 14:12:15
User entered '6'	System	02 Nov 2020 15:22:19
User entered '5'	System	30 Oct 2020 13:58:29
User entered '4'	System	21 Oct 2020 16:35:42
User entered '3'	System	14 Oct 2020 13:51:59
User entered '2'	System	12 Oct 2020 15:58:20
User entered '1'	System	02 Oct 2020 12:35:56

FDA-CBER-2022-1614-0006401

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form (14)
Generated On: 09 Jun 2021 14:54:12
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	09 Dec 2020 15:42:07
User entered '08/Dec/2020 09:58'	System	08 Dec 2020 14:58:45

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form (14)

Generated On: 09 Jun 2021 14:54:12

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) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	14 Jan 2021 16:31:38
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	09 Dec 2020 15:42:07
User entered '1'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	08 Dec 2020 14:58:45

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4), (b) (6) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
Un-reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:47
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:43
User entered 'USA-US006-2020-MRNA-1273-P301000002'	System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006404

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Yes (Y)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006405

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Yes (Y)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006408

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006409

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006411

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Laurence'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Chu'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006413

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered '3100 Red River Street'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006414

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Austin'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006415

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'TX'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006416

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered '78705'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006417

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	12 Oct 2020 15:58:11
User entered 'US'	(b) (4), (b) (6) System	02 Oct 2020 12:35:56

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '18'	System	09 Mar 2021 14:58:51
User entered '17'	System	04 Mar 2021 13:33:28
User entered '16'	System	14 Jan 2021 16:31:53
User entered '15'	System	10 Dec 2020 19:04:59
User entered '14'	System	08 Dec 2020 14:58:45
User entered '13'	System	05 Dec 2020 17:59:24
User entered '12'	System	25 Nov 2020 18:59:34
User entered '11'	System	19 Nov 2020 17:47:54
User entered '10'	System	19 Nov 2020 16:31:32
User entered '9'	System	11 Nov 2020 16:58:44
User entered '8'	System	06 Nov 2020 17:51:29
User entered '7'	System	04 Nov 2020 14:12:15
User entered '6'	System	02 Nov 2020 15:22:19
User entered '5'	System	30 Oct 2020 13:58:29
User entered '4'	System	21 Oct 2020 16:35:42
User entered '3'	System	14 Oct 2020 13:51:59
User entered '2'	System	12 Oct 2020 15:58:20
User entered '1'	System	02 Oct 2020 12:35:56

FDA-CBER-2022-1614-0006419

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form (15)
Generated On: 09 Jun 2021 14:54:12
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:19:16
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '10/Dec/2020 14:04'	System	10 Dec 2020 19:04:59

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form (15)

Generated On: 09 Jun 2021 14:54:12

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) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:19:16
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	14 Jan 2021 16:31:38
User entered '1'	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 19:04:59

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4), (b) (6) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
Un-reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:47
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:43
User entered 'USA-US006-2020-MRNA-1273-P301000002'	System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006422

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Yes (Y)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006423

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006424

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006425

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Yes (Y)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006426

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006427

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006429

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Laurence'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Chu'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006431

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered '3100 Red River Street'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006432

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Austin'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006433

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'TX'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006434

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered '78705'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006435

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	12 Oct 2020 15:58:11
User entered 'US'	(b) (4), (b) (6) System	02 Oct 2020 12:35:56

FDA-CBER-2022-1614-0006436

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '18'	System	09 Mar 2021 14:58:51
User entered '17'	System	04 Mar 2021 13:33:28
User entered '16'	System	14 Jan 2021 16:31:53
User entered '15'	System	10 Dec 2020 19:04:59
User entered '14'	System	08 Dec 2020 14:58:45
User entered '13'	System	05 Dec 2020 17:59:24
User entered '12'	System	25 Nov 2020 18:59:34
User entered '11'	System	19 Nov 2020 17:47:54
User entered '10'	System	19 Nov 2020 16:31:32
User entered '9'	System	11 Nov 2020 16:58:44
User entered '8'	System	06 Nov 2020 17:51:29
User entered '7'	System	04 Nov 2020 14:12:15
User entered '6'	System	02 Nov 2020 15:22:19
User entered '5'	System	30 Oct 2020 13:58:29
User entered '4'	System	21 Oct 2020 16:35:42
User entered '3'	System	14 Oct 2020 13:51:59
User entered '2'	System	12 Oct 2020 15:58:20
User entered '1'	System	02 Oct 2020 12:35:56

FDA-CBER-2022-1614-0006437

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form (16)
Generated On: 09 Jun 2021 14:54:12
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:19:16
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '14/Jan/2021 11:31'	System	14 Jan 2021 16:31:53

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form (16)

Generated On: 09 Jun 2021 14:54:12

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) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:19:16
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 13:33:13
User entered '1'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	14 Jan 2021 16:31:53

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4), (b) (6) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
Un-reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:47
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:43
User entered 'USA-US006-2020-MRNA-1273-P301000002'	System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006440

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Yes (Y)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006441

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006442

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006443

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Yes (Y)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006444

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006445

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006447

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Laurence'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Chu'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006449

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered '3100 Red River Street'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Austin'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006451

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'TX'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered '78705'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006453

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	12 Oct 2020 15:58:11
User entered 'US'	(b) (4), (b) (6) System	02 Oct 2020 12:35:56

FDA-CBER-2022-1614-0006454

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '18'	System	09 Mar 2021 14:58:51
User entered '17'	System	04 Mar 2021 13:33:28
User entered '16'	System	14 Jan 2021 16:31:53
User entered '15'	System	10 Dec 2020 19:04:59
User entered '14'	System	08 Dec 2020 14:58:45
User entered '13'	System	05 Dec 2020 17:59:24
User entered '12'	System	25 Nov 2020 18:59:34
User entered '11'	System	19 Nov 2020 17:47:54
User entered '10'	System	19 Nov 2020 16:31:32
User entered '9'	System	11 Nov 2020 16:58:44
User entered '8'	System	06 Nov 2020 17:51:29
User entered '7'	System	04 Nov 2020 14:12:15
User entered '6'	System	02 Nov 2020 15:22:19
User entered '5'	System	30 Oct 2020 13:58:29
User entered '4'	System	21 Oct 2020 16:35:42
User entered '3'	System	14 Oct 2020 13:51:59
User entered '2'	System	12 Oct 2020 15:58:20
User entered '1'	System	02 Oct 2020 12:35:56

FDA-CBER-2022-1614-0006455

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form (17)
Generated On: 09 Jun 2021 14:54:12
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:19:16
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	05 Mar 2021 19:09:37
User entered '04/Mar/2021 08:33'	System	04 Mar 2021 13:33:28

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form (17)

Generated On: 09 Jun 2021 14:54:12

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) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:19:16
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:58:34
User signature succeeded.	Laurence Chu (b) (4)	05 Mar 2021 19:09:37
User entered '1'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 13:33:28

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
SAEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	Laurence Chu (b) (4) (b) (4), (b) (6) (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
Un-reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:47
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:43
User entered 'USA-US006-2020-MRNA-1273-P301000002'	System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006458

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Yes (Y)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006459

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006461

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Yes (Y)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006462

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006463

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'No (N)'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006465

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Investigator's First Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Laurence'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006466

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Investigator's Last Name

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Chu'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered '3100 Red River Street'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006468

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'Austin'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006469

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: State

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered 'TX'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006470

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Site Address: Postal Code

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 12:35:50
User entered '78705'	(b) (4), (b) (6) System	02 Oct 2020 12:35:23

FDA-CBER-2022-1614-0006471

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
Investigator Country

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User signature succeeded.	(b) (4), (b) (6) Laurence Chu (b) (4)	05 Mar 2021 19:09:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 19:30:17
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	12 Oct 2020 15:58:11
User entered 'US'	(b) (4), (b) (6) System	02 Oct 2020 12:35:56

FDA-CBER-2022-1614-0006472

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form
Generated On: 09 Jun 2021 14:54:12
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
User entered '18'	System	09 Mar 2021 14:58:51
User entered '17'	System	04 Mar 2021 13:33:28
User entered '16'	System	14 Jan 2021 16:31:53
User entered '15'	System	10 Dec 2020 19:04:59
User entered '14'	System	08 Dec 2020 14:58:45
User entered '13'	System	05 Dec 2020 17:59:24
User entered '12'	System	25 Nov 2020 18:59:34
User entered '11'	System	19 Nov 2020 17:47:54
User entered '10'	System	19 Nov 2020 16:31:32
User entered '9'	System	11 Nov 2020 16:58:44
User entered '8'	System	06 Nov 2020 17:51:29
User entered '7'	System	04 Nov 2020 14:12:15
User entered '6'	System	02 Nov 2020 15:22:19
User entered '5'	System	30 Oct 2020 13:58:29
User entered '4'	System	21 Oct 2020 16:35:42
User entered '3'	System	14 Oct 2020 13:51:59
User entered '2'	System	12 Oct 2020 15:58:20
User entered '1'	System	02 Oct 2020 12:35:56

FDA-CBER-2022-1614-0006473

US3012098
Folder: SAE USA-US006-2020-MRNA-1273-P301000002
Form: Safety Report Form (18)
Generated On: 09 Jun 2021 14:54:12
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:19:16
User signature succeeded.	Laurence Chu (b) (4) (b) (4)	12 Mar 2021 19:15:26
User entered '09/Mar/2021 08:58'	System	09 Mar 2021 14:58:51

FDA-CBER-2022-1614-0006474

US3012098

Folder: SAE USA-US006-2020-MRNA-1273-P301000002

Form: Safety Report Form (18)

Generated On: 09 Jun 2021 14:54:12

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) (b) (4), (b) (6)	26 Apr 2021 19:35:09
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 20:19:16
User signature succeeded.	Laurence Chu (b) (4)	12 Mar 2021 19:15:26
User entered '1'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 14:58:51